

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PUREWICK CORPORATION,)	
)	
Plaintiff/Counterclaim Defendant,)	
)	C.A. No. 19-1508-MN
v.)	
)	
SAGE PRODUCTS, LLC,)	
)	
Defendant/Counterclaim Plaintiff.)	
)	

[PROPOSED] FINAL JURY INSTRUCTIONS

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I. GENERAL¹

A. INTRODUCTION

Members of the jury, now it is time for me to instruct you about the law that you must follow in deciding this case. Each of you has been provided a copy of these instructions. You may read along as I deliver them if you prefer.

I will start by explaining your duties and the general rules that apply in every civil case. Then I will explain some rules that you must use in evaluating testimony and evidence. Then I will explain the positions of the parties and the law you will apply in this case. Then we will hear the closing arguments. After that, I will explain the rules that you must follow during your deliberations in the jury room, and the possible verdicts that you may return.

You will have a written copy of these instructions with you in the jury room for your reference during your deliberations. You will also have a verdict form, which will list the questions that you must answer to decide this case. We will go over that later.

¹ Authority: Many of the proposed final jury instructions were adapted from the Final Jury Instructions read to the jury in *ArcherDX, LLC et al. v. Qiagen Sciences, LLC et al.*, No. 18-1019 (MN), D.I. 462 (Aug. 27, 2021), unless otherwise indicated.

B. JURORS' DUTIES

You have two main duties as jurors. The first is to decide what the facts are from the evidence that you saw and heard in court. Deciding what the facts are is your job, not mine, and nothing that I have said or done during this trial was meant to influence your decision about the facts in any way. You are the sole judges of the facts.

Your second duty is to take the law that I give you, apply it to the facts, and decide under the appropriate burden of proof which party should prevail on any given issue. It is my job to instruct you about the law, and you are bound by the oath you took at the beginning of the trial to follow the instructions that I give you, even if you personally disagree with them. This includes the instructions that I gave you before and during the trial, and these instructions. All of the instructions are important, and you should consider them together as a whole.

Perform these duties fairly. Do not guess or speculate, and do not let any bias, sympathy, or prejudice you may feel toward one side or the other influence your decision in any way.

C. EVIDENCE DEFINED

You must make your decision based only on the evidence that you saw and heard here in court. Do not let rumors, suspicions, or anything else that you may have seen or heard outside of court influence your decision in any way.

The evidence in this case includes only what the witnesses said while they were testifying under oath, including deposition transcript testimony that has been played by video or read to you, the exhibits that I allowed into evidence, and the stipulations to which the lawyers agreed.

Nothing else is evidence. The lawyers' statements and arguments are not evidence. They are offered solely as an aid to help you in your determination of the facts. The lawyers' questions and objections are not evidence. My legal rulings are not evidence. You should not be influenced by a lawyer's objection or by my ruling on that objection. Any of my comments and questions are not evidence.

During the trial I may have not let you hear the answers to some of the questions that the lawyers asked. I also may have ruled that you could not see some of the exhibits that the lawyers wanted you to see. And, sometimes I may have ordered you to disregard things that you saw or heard, or that I struck from the record. You must ignore all of these things. Do not speculate about what a witness might have said or what an exhibit might have shown. These things are not evidence, and you are bound by your oath not to let them influence your decision in any way. Make your decision based only on the evidence, as I have defined it here, and nothing else.

D. DIRECT AND CIRCUMSTANTIAL EVIDENCE

During the preliminary instructions, I told you about “direct evidence” and “circumstantial evidence.” I will now remind you what each means.

Direct evidence is simply evidence like the testimony of an eyewitness which, if you believe it, directly proves a fact. If a witness testified that he saw it raining outside, and you believe him, that would be direct evidence that it was raining.

Circumstantial evidence is simply a chain of circumstances that indirectly proves a fact. If someone walked into the courtroom wearing a raincoat covered with drops of water and carrying a wet umbrella, that would be circumstantial evidence from which you could conclude that it was raining.

It is your job to decide how much weight to give the direct and circumstantial evidence. You should consider all the evidence, both direct and circumstantial, and give it whatever weight you believe it deserves.

E. CONSIDERATION OF EVIDENCE

You should use your common sense in weighing the evidence. Consider it in light of your everyday experience with people and events and give it whatever weight you believe it deserves. If your experience tells you that certain evidence reasonably leads to a conclusion, you are free to reach that conclusion.

F. CREDIBILITY OF WITNESSES

You are the sole judges of each witness's credibility. You may believe everything a witness says, or part of it, or none of it. You should consider each witness's means of knowledge; strength of memory; opportunity to observe; how reasonable or unreasonable the testimony is; whether it is consistent or inconsistent; whether it has been contradicted; the witness's biases, prejudices, or interests; the witness's manner or demeanor on the witness stand; and all circumstances that, according to the evidence, could affect the credibility of the testimony.

In determining the weight to give to the testimony of a witness, you should ask yourself whether there is evidence tending to prove that the witness testified falsely about some important fact or whether there was evidence that at some other time the witness said or did something, or failed to say or do something, that was different from the testimony he or she gave at the trial in person or by deposition testimony played by video or read to you. You have the right to distrust such witness's testimony and you may reject all or some of the testimony of that witness or give it such credibility as you may think it deserves.

G. EXPERT WITNESSES

Expert testimony is testimony from a person who has a special skill or knowledge in some science, profession, or business. This skill or knowledge is not common to the average person but has been acquired by the expert through special study or experience.

In weighing expert testimony, you may consider the expert's qualifications, the reasons for the expert's opinions, and the reliability of the information supporting the expert's opinions, as well as the factors I have previously mentioned for weighing testimony of any other witness. Expert testimony should receive whatever weight and credit you think appropriate, given all the other evidence in the case.

H. DEPOSITION TESTIMONY

During the trial, certain testimony was presented to you by playing the video excerpts or reading from a deposition. The deposition testimony may have been edited or cut to exclude irrelevant testimony as the parties have only a limited amount of time to present you with evidence. You should not attribute any significance to the fact that the depositions may appear to have been edited. Deposition testimony is out of court testimony given under oath and is entitled to the same consideration you would give it had the witnesses personally appeared in court.

I. DISPUTED: SPOLIATION

Defendant's Proposal:² Sage contends that PureWick failed to preserve evidence after its duty to preserve arose. This failure to preserve is known as “spoliation of evidence.” Spoliation is the destruction or material alteration of evidence or the failure to preserve evidence for another's use in pending or reasonably foreseeable litigation. Spoliation occurs where evidence was in a party's control; the evidence is relevant to the claims or defenses in the case; there has been actual suppression or withholding of evidence; and, the duty to preserve the evidence was reasonably foreseeable to the party.

If you find there has been spoliation, you may, but are not required, to presume that the lost evidence would have been relevant and helpful to Sage's case and/or would have been harmful to PureWick's case. Alternatively, you may infer that the evidence not produced would merely have been duplicative of, or similar to, the evidence before you. If you find spoliation, your role is to determine whether PureWick's spoliation tilted the playing field against Sage. If so, the permission given to you to infer that the missing documents would have been relevant and helpful to Sage and/or harmful to PureWick is designed to allow you to balance that playing field, should you feel it is necessary.

It is up to you to decide the extent to which the lost evidence was relevant and helpful to Sage and/or harmful to PureWick. Of course, it is impossible to know exactly what evidence was lost - although the parties have tried - so you must make these determinations to the best of your

² Due to length, parties disputes are in footnotes on the following page.

ability based on all of the facts and circumstances of this case. You must then decide how much weight and effect to give to your belief about spoliation in reaching your verdict.^{3, 4}

³ Defendant's instruction was adapted from *GN Netcom, Inc. v. Plantronics, Inc.*, C.A. No. 12-1318-LPS, D.I. 532, § 5 (D. Del. Oct. 18, 2017); *see also Bull v. UPS*, 665 F.3d 68, 73 (3d Cir. 2012). An evidentiary instruction regarding spoliation is appropriate here. Late in discovery, Sage learned that PureWick failed to preserve a legacy email server from the original PureWick company and lost responsive information from critical time periods. (*See* D.I. 207, Ex. 18 at pp. 45, 77-78.) Contrary to PureWick's argument, spoliation has long been an issue in this case (*id.*) and there has been various discovery about it including a Rule 30(b)(6) deposition. (D.I. 210, Ex. 28 at ¶57.) PureWick was well aware of Sage's contentions regarding the spoliation:

[W]ell into this litigation, PureWick advised Sage (after the parties had already exchanged and agreed upon search procedures for electronic searching) that PureWick failed to preserve a legacy PureWick server. ...[T]his server contained critical information relating to Sage's defenses, including its prior art defense relating to the on-sale bar. ... PureWick's email is highly germane to issues in this case. Four of the six identified PureWick custodians are legacy PureWick employees. The email would contain historical communications and information related to development of the PureWick products and patents, invalidating disclosures to third parties, prior art, and other information regarding inventors, most or all of which would have been from a time period prior to the PureWick acquisition.... Indeed, one of the invalidity issues ... revolves around PureWick's disclosures to third parties (including via email) prior to the priority date, which occurred before the acquisition. ... PureWick was under the obligation to preserve PureWick email at the time the server was "shut down" in early to mid-2019..... Particularly troubling is that Sage was unaware that....emails were irrecoverable when the parties were negotiating the email searching protocols ...because PureWick did not inform Sage that PureWick/Bard failed to preserve them at that time. Many of the search terms that Sage identified were prior art terms or terms relating to prior communications on invalidating disclosures. Sage has been significantly prejudiced in its ability to present its defenses due to PureWick's failure to preserve evidence. ...

(D.I. 207, Ex. 18, at pp. 45, 77-78.) "Spoliation occurs where: the evidence was in the party's control; the evidence is relevant to the claims or defenses in the case; there has been actual suppression or withholding of evidence; and, the duty to preserve the evidence was reasonably foreseeable to the party." *Bull*, 665 F.3d at 73. There is no dispute that PureWick failed to preserve evidence, and PureWick has never provided an explanation. This issue is thus ripe for review and a corollary instruction. *GN Netcom, Inc. v. Plantronics, Inc.*, 930 F.3d 76, 83 (3d Cir. 2019) ("permissive adverse inference instruction" is a "lesser sanction"); *West v. Tyson Foods*, 374 F. App'x 624, 635 (6th Cir. 2010) (spoliation instruction is "simply a formalization of what the jurors would be entitled to do even in the absence of a specific instruction."); *Mali v. Fed. Ins. Co.*, 720 F.3d 387, 393 (2d Cir. 2013).

J. USE OF NOTES

You may have taken notes during trial to assist your memory. As I instructed you at the beginning of the case, you should use caution in consulting your notes. There is generally a tendency to attach undue importance to matters which one has written down. Some testimony which is considered unimportant at the time presented, and thus not written down, takes on greater

⁴ Plaintiff objects to Defendant's proposed spoliation instruction. Defendants never made a "contention" in this case that PureWick failed to preserve evidence, nor did Defendants ever raise such an issue with the Court. Defendant's proposed instruction is considered a sanction under Rule 37(e)(2)(B). The sanctions discussed in Rule 37(e) are within *the Court's* inherent power to order. *See Citrix Sys., Inc. v. Workspot, Inc.*, No. CV 18-588-LPS, 2020 WL 5884970, at *6 (D. Del. Sept. 25, 2020). Sage never moved for sanctions under Rule 37(e), nor has it presented any evidence that it is entitled to such sanctions. Contrary to Sage's assertion, PureWick does dispute Sage's claims that PureWick "failed to preserve evidence" and that "PureWick has never provided an explanation." PureWick provided deposition testimony that it actively preserved evidence prior to trial and explained to Sage multiple times that the server in question had been lost. *See Bull v. United Parcel Serv., Inc.*, 665 F.3d 68, 73 (3d Cir. 2012) ("For the [spoliation] rule to apply . . . it must appear that there has been an actual suppression or withholding of the evidence. No unfavorable inference arises when the circumstances indicate that the document or article in question has [merely] been lost or accidentally destroyed, or where the failure to produce it is otherwise properly accounted for."). Moreover, the Court may order sanctions under Rule 37(e) only "upon finding prejudice to another party from loss of the information." Fed. R. Civ. P. 37(e)(1). And a finding of prejudice requires the non-spoliating party to "come forward with plausible, concrete suggestions as to what the lost evidence might have been" and a showing that the loss of this evidence "materially affect[ed] the substantial rights of the adverse party and is prejudicial to the presentation of the case." *Monolithic Power Sys., Inc. v. Intersil Corp.*, 2018 WL 6075046, at *1 (D. Del. Nov. 19, 2018); *CIGNEX Datamatics, Inc. v. Lam Rsch. Corp.*, No. CV 17-320 (MN), 2019 WL 1118099, at *5 (D. Del. Mar. 11, 2019) (finding that "***Lam's suggestion as to the potential contents of the lost emails appears to be speculation***" and thus "there is insufficient evidence of prejudice and "a curative measure under Rule 37(e)(1) is inappropriate") (emphasis added). Sage has never done this. Finally, *the adverse inference instruction that Sage proposes is a sanction warranted "only upon finding that the party acted with the intent to deprive another party of the information's use in the litigation"* Fed. R. Civ. P. 37(e)(2)(B) (emphasis added); *see also Bull*, 665 F.3d at 79 ("[A] finding of bad faith is pivotal to a spoliation determination."); *CIGNEX*, 2019 WL 1118099 at *4 ("Lam fails to point to any facts that support a finding that CIGNEX acted in bad faith . . . as required by Rule 37(e)(2)."). Sage has never demonstrated, nor can it, that PureWick acted with the requisite intent to support its proposed instruction.

importance later in the trial in light of all the evidence presented. Therefore, your notes are only a tool to aid your own individual memory, and you should not compare notes with other jurors in determining the content of any testimony or in evaluating the importance of any evidence.

Your notes are not evidence and are by no means a complete outline of the proceedings or a list of the highlights of the trial. Above all, your memory should be the greatest asset when it comes time to deliberate and render a decision in this case.

K. DISPUTED: BURDENS OF PROOF

1. Plaintiff's Proposal⁵

In any legal action, facts must be proven by a required standard of evidence, known as the “burden of proof.”

In a patent case such as this, there are two different burdens of proof. The first is called “preponderance of the evidence.” The second is called “clear and convincing evidence.” I told you about these two standards of proof during my preliminary instructions to you and I will now remind you what they mean.

The Plaintiff, PureWick, has accused the Defendant, Sage, of infringing claims of three patents and contends that the infringement was willful. Sage denies those allegations. It contends that the asserted patent claims in this case are invalid.

PureWick has the burden of proving its claims and the amount of monetary damages by a preponderance of the evidence. This means PureWick has to produce evidence which, when considered in light of all the facts, leads you to believe that what PureWick claims is more likely true than not. To put it differently, if you were to put PureWick's and Sage's evidence on the opposite sides of the scale, the evidence supporting PureWick's claims would have to make the scales tip somewhat to its side. If the scale should remain equal or tip in favor of Sage, you must find for Sage.

⁵ Plaintiff's proposed instruction is taken directly from the Court's Final Jury Instruction in *ArcherDX, LLC et al. v. Qiagen Sciences, LLC et al.*, No. 18-1019 (MN), D.I. 462 (Aug. 27, 2021). Defendants' proposed instruction is confusing because it addresses the standards for each burden of proof in the abstract, rather than in connection with the issues the jury must decide. Defendants also reference an assertion that the patents-in-suit are “unenforceable,” which is not an issue for the jury.

In addition to denying PureWick's claims that they infringe, Sage asserts that all of the asserted patent claims are invalid. Sage has the burden of proving that the asserted claims are invalid and has to do so by clear and convincing evidence. Clear and convincing evidence is evidence that persuades you that what Sage seeks to prove is highly probable. Proof by clear and convincing evidence is thus a higher burden of proof than proof by a preponderance of the evidence.

You may have heard of the "beyond a reasonable doubt" burden of proof from criminal cases. That requirement is the highest burden of proof in our judicial system. It applies in criminal cases, but does not apply to civil cases, like this one, and, therefore, you should put it out of your mind.

2. Defendant's Proposal⁶

In any legal action, facts must be proven by a required standard of evidence, known as the "burden of proof."

The Plaintiff, PureWick, has accused the Defendant, Sage, of infringing claims of three patents and contends that the infringement was willful. The Defendant denies those allegations and contends that the asserted patent claims in this case are invalid and unenforceable.

In a patent case such as this, there are two different burdens of proof. The first is called "preponderance of the evidence." The second is called "clear and convincing evidence." I told you

⁶ Sage's proposal also follows *ArcherDX* case and numerous paragraphs are identical to Plaintiff's; however, there are additional issues in this case that were not present in *ArcherDX*. Thus, minor modifications are made relevant to the facts of this case. First, PureWick's proposal excludes numerous aspects of this case that it needs to prove. Sage's proposal therefore moves the paragraph with the explanation of the burden first and then follows with examples relevant to this case. PureWick has made no objection to any substance of Sage's modifications as they simply more accurately reflect this case.

about these two standards of proof during my preliminary instructions to you and I will now remind you what they mean.

For any issue on which a party bears the burden of proof by a preponderance of the evidence, that party has carried its burden if you find that what the party claims is more likely true than not, when considered in light of all the evidence. To put it differently, if you were to put each party's evidence on the opposite sides of the scale, the evidence supporting the party with the burden of proof would have to make the scales tip somewhat to its side. If the scale should remain equal or tip in favor of the other party, you must find for the other party.

Here, Plaintiff has the burden of proving by a preponderance of the evidence that Sage has infringed the '376, '989, and '407 patents, the priority date of its inventions, and the amount of damages Plaintiff should receive to compensate them for any infringement.

For any issue on which a party bears the burden of proof by clear and convincing evidence, that party has carried its burden if you find what the party claims is highly probable, when considered in light of all the evidence. Proof by clear and convincing evidence is thus a higher burden of proof than proof by a preponderance of the evidence. In addition to denying Plaintiff's claims that they infringe, the Defendant asserts that all of the asserted patent claims are invalid. Here, the Defendant has the burden of proving by clear and convincing evidence that the asserted claims are invalid.

You may have heard of the "beyond a reasonable doubt" burden of proof from criminal cases. That requirement is the highest burden of proof in our judicial system. It applies in criminal cases, but does not apply to civil cases, like this one, and, therefore, you should put it out of your mind.

II. PATENT JURY INSTRUCTIONS

A. DISPUTED: GENERAL

PureWick has accused Sage of infringing the claims of three of PureWick's patents: U.S. Patent Nos. 10,266,376, 10,390,989 and 10,376,407. As you have heard during this trial, we refer to those patents as the '376, '989 and '407 Patents, respectively, and we sometimes refer to them collectively as "the patents-in-suit."

PureWick contends that Sage literally infringes claims 1, 5, and 9 of the '376 patent by making, using, offering to sell, and selling the PrimaFit device.

Further, PureWick contends that Sage indirectly infringes claims 1, 5 and 9 of the '376 patent by inducing or contributing to infringement by others.

PureWick also contends that Sage literally infringes claims 1, 2, and 6 of the '989 patent by using the PrimaFit device. Further, PureWick contends that Sage indirectly infringes claims 1, 2, and 6 of the '989 patent by inducing or contributing to infringement by others.

PureWick also contends that Sage literally infringes claims 1, 2, 7, and 13 of the '407 patent by making, using, offering to sell, and selling the PrimoFit device. PureWick also contends, alternatively, that Sage infringes claim 2 of the '407 patent under the doctrine of equivalents by making, using, offering to sell, or selling the PrimoFit device.

PureWick contends that Sage has willfully infringed the '376 and '989 patents.

I may refer to the PrimaFit and PrimoFit collectively as "the Accused Products."

Sage denies that it literally infringes claims 1, 5, and 9 of the '376 patent by making, offering to sell, and selling the PrimaFit device.

Further, Sage denies that it indirectly infringes claims 1, 5 and 9 of the '376 patent by inducing or contributing to infringement by others.

Sage denies that it literally infringes claims 1, 2, and 6 of the '989 patent by using the PrimaFit device.

Further, Sage denies that it indirectly infringes claims 1, 2, and 6 of the '989 patent by inducing or contributing to infringement by others.

Sage also denies that it literally infringes claims 1, 2, 7, and 13 of the '407 patent by making, offering to sell, and selling the PrimoFit device. Sage denies that it infringes claim 2 of the '407 patent under the doctrine of equivalents by making, offering to sell, or selling the PrimoFit device

Sage also denies that it has willfully infringed any patents-in-suit.

Sage also contends that claims 1, 5, and 9 of the 376 patent and claims 1, 2, and 6 of the 989 patent are invalid as anticipated by the prior art. Sage contends, alternatively, that claims 1, 5, and 9 of the 376 patent and claims 1, 2, and 6 of the 989 patent are invalid because they would have been obvious to a person of ordinary skill in the art.

Sage contends that claims 1, 2, 7, and 13 of the 407 patent are invalid as anticipated by the prior art and would have been obvious to a person of ordinary skill in the art. Sage also contends

that claim 7 of the 407 patent is invalid because it lacks an adequate written description [**Sage further proposes:** and is indefinite.^{7, 8}]

Your job is to decide whether Sage has infringed each of the asserted claims of the '376, '989 and '407 patents and whether each asserted claim is invalid. You will also need to make a finding as to whether any infringement of the '376 and '989 patents was willful.

⁷ The issue of indefiniteness is addressed further below in Instruction II.V. PureWick contends that indefiniteness is a matter of law; however, indefiniteness is based on underlying fact determinations that are appropriate for the jury. *Green Edge Enters. v. Rubber Mulch Etc.*, 620 F.3d 1287, 1299 (Fed. Cir. 2010); *see Pac. Biosciences of Ca., Inc. v. Oxford Nanopore Techs., Inc.*, No. CV 17-1353-LPS-CJB, 2020 WL 4699049, at *11 (D. Del. Aug. 13, 2020), *aff'd*, 996 F.3d 1342 (Fed. Cir. 2021) (appropriate to put indefiniteness before the jury); *Bombardier Recreational Prod. Inc. v. Arctic Cat Inc.*, 785 F. App'x 858, 866 (Fed. Cir. 2019). Notably, PureWick opposed Sage's summary judgment motion on indefiniteness. (D.I. 235 at 1-2, 22-23.)

⁸ As noted in Instruction II.V, it is Plaintiff's position that indefiniteness is a question of law and thus should be decided by the Court, not the jury. *See Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1341 (Fed. Cir. 2015) ("Indefiniteness is a question of law."). Contrary to Sage's argument, there is no factual dispute to be resolved by the jury, nor has Sage identified one.

B. THE CLAIMS OF A PATENT

Before you can decide many of the issues in this case, you will need to understand the role of patent “claims.” The patent claims are the numbered sentences at the end of a patent. The claims describe the invention and describe what the patent owner may prevent others from doing.

Patent claims may exist in two forms, referred to as independent claims or dependent claims. An independent claim does not refer to any other claim of the patent. Thus, it is not necessary to look at any other claim to determine what an independent claim covers. For example, claim 1 of the ’376 patent is an independent claim.

A dependent claim refers to at least one other claim in the patent. A dependent claim includes each of the limitations of the other claims or claims to which it refers, as well as the additional limitations of the dependent claim itself. Therefore, to determine what a dependent claim covers, it is necessary to look at both the dependent claim and the other claim or claims to which it refers. For example, claim 4 of the ’376 patent is a dependent claim. To determine what dependent claim 4 of the ’376 patent covers, the words of that claim and the words of independent claim 1 of the ’376 patent must be read together.

It is my job as a judge to define the terms of the claims and to instruct you about the meaning. You must apply my definitions to the issues that you are asked to decide. I have determined the meaning of the following terms of the asserted claims of the ’376 and ’989 patents:

- “casing having a fluid reservoir at a first end [and] . . . , a fluid outlet at a second end . . .” means “an outer cover having a fluid reservoir at a first end and a fluid outlet at a second end” (’376 Patent, claim 1; ’989 Patent, claim 1);
- “wicking material” means “an article that moves moisture by capillary action from one surface of the article to the other” (’376 patent, claim 9). Wicking material in the ’407 patent also has this same meaning (’407 patent, claims 1, 7, and 13).

I have also determined the meaning of the following additional terms of the asserted claims of the '407 patent:

- “the chamber being defined at least partially by . . . the porous material and the . . . layer of impermeable material” and “the chamber being [partially] defined by a portion of the . . . porous material and a portion of the impermeable material” will be given their plain and ordinary meanings with the clarification to be at least partially defined by the porous material and the impermeable layer, the porous material and the impermeable layer must each touch the chamber at some point (407 patent, claims 1, 7, 13)

You must accept my definition of these words as being correct. It is your job to take these definitions and apply them to the issues that you are deciding, including the issues of infringement and invalidity.

For any words in the claim for which I have not provided you with a definition, you should apply their ordinary meaning in the field of the patents. You should not take my definition of the language of the claims as an indication that I have a view regarding how you should decide the issues that you are being asked to decide, such as infringement and invalidity. These issues are yours to decide.⁹

⁹ Sage reserves all rights with respect to constructions for which Sage offered a different construction.

C. INFRINGEMENT – GENERALLY

I will now instruct you as to the rules you must follow when deciding whether PureWick has proven that Sage has infringed the patents-in-suit. The United States' patent law gives the owner of a valid patent the right to exclude others from importing, making, using, offering to sell, or selling the patented product or method in the United States during the term of the patent. Any person or company that has engaged in any of those acts without the patent owner's permission infringes the patent.

Infringement is assessed on a claim-by-claim basis. Therefore, there may be infringement of one claim but no infringement of another. In this case, there are three possible ways that a claim may be infringed. The three types are called: (1) direct infringement; (2) induced infringement; and (3) contributory infringement. Induced infringement and contributory infringement are referred to as indirect infringement. PureWick alleges that Sage has directly infringed the asserted claims of the 407 patent. PureWick alleges that Sage has directly and indirectly infringed the asserted claims of the 376 and 989 patents.

D. DISPUTED: DIRECT, LITERAL INFRINGEMENT

There are two types of “direct infringement”: (1) “literal infringement” and (2) “infringement under the doctrine of equivalents.” In this case, both types of direct infringement are at issue. You must determine whether PureWick has proven literal infringement of the asserted claims of the 376, 989 and 407 patents. For claim 2 of the 407 patent only, you must also determine whether PureWick has proven infringement under the doctrine of equivalents.

In order to prove literal infringement of the claims of the 376 and 407 patents, PureWick must prove by a preponderance of the evidence, i.e., that it is more likely than not, that Sage made, used, offered for sale, or sold in the United States, a device that meets all of the requirements of the asserted claims of those patents. In order to prove literal infringement of the method claims of the 989 patent, PureWick must prove by a preponderance of the evidence, i.e., that it is more likely than not, that Sage performed each of the steps of the asserted claims of the 989 patent.

You must determine, separately for each asserted claim of the '376, '989 and '407 patents whether or not there is infringement. There is one exception to this rule. If you find that an independent claim is not infringed, there cannot be infringement of any dependent claim that refers directly or indirectly to that claim. On the other hand, if you find that an independent claim has been infringed, you must still separately decide whether the accused devices and methods meet additional requirements of any claims that depend from the independent claim to determine whether the dependent claims have also been infringed. Remember, a dependent claim includes all the requirements of any of the claims to which it refers plus additional requirements of its own.

1. Plaintiff's Additional Proposal¹⁰

You must compare the PrimaFit device with each asserted claim of the '376 patent, use of the PrimaFit device with each asserted claim of the '989 patent, and the PrimoFit product with each asserted claim of the '407 patent, to determine whether each and every one of the requirements of a given claim is satisfied. The same element of the accused product may satisfy more than one element of a patent claim.¹¹ When performing this comparison, you should be careful not to compare the accused Sage products with PureWick's products or the descriptions in the '376, '989 and '407 patents.

The presence of additional elements in an accused device or method of using a device does not mean that the device or method does not infringe a patent claim. Whether or not Sage's products or use of the products represents an improvement either over the patent claims or over another device is not relevant to whether or not Sage infringes PureWick's asserted patent claims. As long as the Accused Product includes all of the elements of an asserted patent claim, then that patent claim is infringed by the Accused Product even if that product also has additional elements.

You may find direct infringement based on one instance of the claimed product being made, used, offered for sale, or sold by Sage. Proof of direct infringement may be based on circumstantial evidence.

¹⁰ With the exception of one sentence (noted below), Plaintiff's proposed instruction is taken from the Court's Final Jury Instruction in *ArcherDX, LLC et al. v. Qiagen Sciences, LLC et al.*, No. 18-1019 (MN), D.I. 462 (Aug. 27, 2021) with alterations made only to account for the fact that in this case, as opposed to in *ArcherDX*, Plaintiff's allege direct, literal infringement for more than one patent and for infringement of a method. Defendant provides no support for its edits and additions (reflected below in its proposed instruction), which are confusing and redundant of the agreed upon portions of this instruction.

¹¹ This sentence taken from AIPLA Model Patent Jury Instructions, section 3.2 (2019).

2. Defendant's Additional Proposal¹²

To determine literal infringement of the device claims of the '376 patent, you must compare the PrimaFit device with each asserted claim of the patent to determine whether each and every one of the requirements of a given claim is satisfied.

To determine literal infringement of the method claims of the '989 patent, you must compare the alleged use (if any) by Sage of the PrimaFit device with each asserted method claim of the '989 patent to determine whether Sage performed each and every one of the requirements of a given method step. The '989 patent's method claims are directly infringed by Sage only if Sage performs in the United States each and every step recited in the claims.

To determine literal infringement of the device claims of the '407 patent, you must compare the PrimoFit device with each asserted device claim of the 407 patent to determine whether each and every one of the requirements of a given claim is satisfied.

When performing these comparisons, you should be careful not to compare the accused Sage products with any PureWick product, or the descriptions or figures in the 376, 989 and '407 patents.

The presence of additional elements in an accused device or in a method of using a device does not mean that the device or method does not infringe a patent claim. Whether or not Sage's

¹² Sage's proposal also follows *ArcherDX* case but addresses additional issues in this case that were not present in *ArcherDX*. For example, this case involves methods claims where there is a dispute over direct infringement and split infringement. This is not addressed in PureWick's proposal. Additionally, PureWick's tracking of certain language in *ArcherDX*, e.g., (reference to a "combination") is simply irrelevant here.

Sage further objects to the addition of the additional sentence regarding the issue of whether one element of the accused product may satisfy more than one claim element. It is a self-serving argument that has not been alleged to be an issue in this case and is thus confusing. Nevertheless, to the extent that it is included for infringement, it should be included for invalidity, which PureWick has not proposed.

products or Sage's use of the product represents an improvement either over the patent claims or over another device is not relevant to whether or not Sage infringes.

Whether or not Sage knew that what it was doing was an infringement does not matter. An entity can be a direct infringer of a patent even if it believes in good faith that it is not infringing any patent or even if it does not know of the patent.

E. DISPUTED: DIRECT INFRINGEMENT UNDER THE DOCTRINE OF EQUIVALENTS

If a company makes, sells, or offers to sell within the United States a product that does not literally meet all of the elements of a claim and thus does not literally infringe that claim, there can still be direct infringement if that product satisfies that claim under the “doctrine of equivalents.” Here, in addition to literal infringement, PureWick contends that Sage infringes claim 2 of the ’407 patent under the “doctrine of equivalents.”

Under the doctrine of equivalents, a product infringes a claim if the accused product contains elements [**Plaintiff’s Proposal:** that literally meet or are equivalent to each and every element of the claim; **Defendant’s Proposal:** corresponding to each and every requirement of the claim that is equivalent to, even though not literally met by, the accused product]. You may find that an element is equivalent to [**Plaintiff’s Proposal:** an element; **Defendant’s Proposal:** a requirement] of a claim that is not met literally if a person having ordinary skill in the field of technology of the patent would have considered the differences between them to be “insubstantial” or would have found that the structure: (1) performs substantially the same function and (2) works in substantially the same way (3) to achieve substantially the same result as the [**Plaintiff’s Proposal:** element; **Defendant’s Proposal:** requirement] of the claim.^{13, 14}

¹³ Plaintiff’s proposed language in this paragraph is taken from the Court’s Final Jury Instruction in *ArcherDX, LLC et al. v. Qiagen Sciences, LLC et al.*, No. 18-1019 (MN), D.I. 462 (Aug. 27, 2021). Defendant’s changes to the language are inaccurate as they suggest that for doctrine of equivalents to apply there must be a showing of equivalents for each element of the claim.

¹⁴ Plaintiff inaccurately state that their language is from *ArcherDX*. It is not. Defendant’s two proposals are directly from *ArcherDX*. *ArcherDX* uses the language “requirement” rather than “element.”

In deciding whether [**Plaintiff's Proposal:**¹⁵ an element of the accused product and a claim element; **Defendant's Proposal:**¹⁶ a claim element and structure of a device] are equivalents, you may consider whether, at the time of the alleged infringement, persons of ordinary skill in the field would have known of the interchangeability of the structure of the accused product with the claimed element. However, known interchangeability between the claim element and the [**Plaintiff's Proposal:** element; **Defendant's Proposal:** structure] in the accused product is not necessary to find infringement under the doctrine of equivalents.]

[**Defendant's Additional Proposal:**^{17, 18}

¹⁵ Plaintiff's proposed instruction is taken directly from the Court's Final Jury Instruction in *ArcherDX, LLC et al. v. Qiagen Sciences, LLC et al.*, No. 18-1019 (MN), D.I. 462 (Aug. 27, 2021) with alterations made only to account for the fact that in this case, as opposed to in *ArcherDX*, Plaintiff alleges infringement under the doctrine of equivalents for an apparatus claim, not a method claim as was in the case in *ArcherDX*. Defendant's proposed instruction mixes out-of-context statements from a number of different cases in a way that is both confusing and prejudicial, most particularly in the last three paragraphs of its proposed instruction.

¹⁶ PureWick is not following *ArcherDX* by adding "an element of the accused product." Sage's proposal tracks the language in *ArcherDX* by not referring to the accused products as having "elements".

¹⁷ The additional items here are adapted from *Bio-Rad Labs., Inc. v. 10X Genomics, Inc.*, No. 15-152-RGA, D.I. 470 (D. Del. Nov. 13, 2018) and The Federal Circuit Bar Association Model Patent Jury Instructions § B.3 at 3.1d (2016). They are included as they are relevant to this case and can assist the jury in understanding equivalence. For example, PureWick's proposal does not address claim vitiation (at issue here). Moreover, PureWick's proposal does not address the relevance of other patents. *See Siemens Med. Sols. USA, Inc. v. Saint-Gobain Ceramics & Plastics, Inc.*, 637 F.3d 1269, 1280 (Fed. Cir. 2011); *Zygo Corp. v. Wyko Corp.*, 79 F.3d 1563, 1570 (Fed. Cir. 1996).

¹⁸ Sage's additional proposal does not add items relevant to this case, nor will it assist the jury in understanding equivalence. The first paragraph of Sage's instruction is not relevant to this case because Sage has never shown that its accused product is covered by a patent. Indeed this issue is the subject of PureWick's Motion in Limine No. 1. *See* JPTO Schedule F1.

In determining whether the differences between a claimed product and the accused product is insubstantial, you may consider the nonobviousness of the accused product as evidenced by the grant of a United States patent on the accused product.

You may not determine that an alternative aspect of a product is equivalent to an unmet requirement of a claim if a finding of infringement under the doctrine of equivalents would effectively eliminate that requirement. Specifically, the alleged equivalent cannot eliminate or ignore an element or requirement of the claim.] **[Both parties:]** In order to prove infringement by “equivalents,” PureWick must prove the equivalency of the structure in the accused product to the claim element in Claim 2 of the 407 patent by a preponderance of the evidence.

F. DISPUTED: INDIRECT INFRINGEMENT: ACTIVE INDUCEMENT

1. Plaintiff's Proposal¹⁹

PureWick also accuses Sage of actively inducing third parties to directly infringe the asserted claims of the '376 and '989 patents. As with direct infringement, you must determine whether there has been inducement on a claim-by-claim basis.

To find that Sage actively induced its customers to infringe, PureWick must prove by a preponderance of the evidence that:

1. A third-party directly infringes the claim;

and that Sage actively induced these acts of infringement, meaning that:

2. Sage aided, instructed, or otherwise acted with the intent to cause acts by third-parties that would constitute direct infringement of the patent;
3. Sage knew of the patent at that time; and
4. Sage knew that the acts, if taken, would constitute infringement of the patent or that Sage believed there was a high probability that the acts by the third-party infringed the patent and took deliberate steps to avoid learning of that infringement.]

2. Defendant's Proposal²⁰

Plaintiff also accuses Sage of actively inducing hospitals and patients to directly infringe the asserted claims of the '376 and '989 patents. As with direct infringement, you must determine whether there has been inducement on a claim-by-claim basis.

¹⁹ Plaintiff's proposed instruction is taken from the Court's Final Jury Instruction in *ArcherDX, LLC et al. v. Qiagen Sciences, LLC et al.*, No. 18-1019 (MN), D.I. 462 (Aug. 27, 2021) with alterations made only to incorporate the definition of willful blindness into No. 4, instead of laying it out separately as the Court did in *ArcherDX*. Defendant's proposed instruction includes only parts of § B.3.2 of the Federal Circuit Bar Association's Model Instructions in a way that is confusing and prejudicial.

²⁰ Sage's instruction is taken from the Federal Circuit Bar Association Model Patent Jury Instructions § B.3 at 3.2 (2020) as well as *Bio-Rad Laboratories, Inc. et al. v. 10X Genomics, Inc.*,

To find that Sage actively induced its customers to infringe, Plaintiff must prove by a preponderance of the evidence that:

1. Hospital and patients directly infringe the claim by carrying out infringing acts (I will explain more shortly on what constitutes direct infringement by these parties);
2. Sage took action during the time the asserted patent was in force intending to cause the infringing acts by hospitals and patients; and
3. Sage was aware of the particular patent at issue (the 376 and 989 patent) and knew that the acts, if taken by hospitals and patients, would constitute infringement of that particular patent.

If you find that Sage was aware of the 376 and 989 patents, but believed that the acts it encouraged did not infringe that patent, Sage cannot be liable for inducement.

In order to establish induced infringement, it is not sufficient that hospitals and patients directly infringe the claim. Nor is it sufficient that Sage was aware of the acts the hospitals and patients that constitute the direct infringement. Rather, in order to find induced infringement, you must find that Sage specifically intended hospitals and patients to infringe. The mere fact, if true, that Sage knew or should have known that there was a substantial risk that another party's acts would infringe would not be sufficient for induced infringement.

No. 15-152-RGA, D.I. 470 (D. Del. Nov. 13, 2018), which is more relevant to aspects of this case. As a preliminary matter, “willful blindness” has never been alleged in this case and PureWick removed references to willful blindness elsewhere when adopting *ArcherDX* instructions. Indeed, the patents-in-suit issued after Sage's product was on the market and PureWick sued shortly after issuance. PureWick's instruction is also deficient because it does not address a key issue in this case—that the alleged inducement involves split infringement issues. Indeed, PureWick's veers from *ArcherDX* in that it switches between inducing “customers” and yet requires acts by unidentified “third parties.” This is not an accurate reflection of the law. Additional discussion of split infringement is discussed in Instruction G below.

G. DISPUTED: INDIRECT INFRINGEMENT: ACTS OF MULTIPLE PARTIES COMBINED TO MEET ALL CLAIM LIMITATIONS FOR DIRECT INFRINGEMENT

Defendant's Proposal:^{21, 22} Direct infringement occurs where all steps of a claimed method are performed by or are attributable to a single party. Where more than one party is involved in practicing the steps, you must determine whether the acts of one are attributable to the other such that a single party is responsible for the infringement. There are two situations where there may be direct infringement if no single party performs all of the steps of a claimed process but more than one party performs every step of the process: (1) the parties have formed a joint enterprise or (2) one party directs or controls the other party's performance of the claim steps.

PureWick alleges that hospitals and patients collectively infringe claims of the 376 and 989 patents.

For infringement to be proven, PureWick must prove by a preponderance of the evidence (1) that all the steps of the claimed process were performed in the United States and (2) that the

²¹ Defendant's instruction is adapted from The Federal Circuit Bar Association Model Patent Jury Instructions § B.3 at 3.7 (2020); *Limelight Networks, Inc. v. Akamai Technologies, Inc.*, 797 F.3d 1020, 1022-24 (Fed. Cir. 2015) (en banc). Contrary to PureWick's assertions below, this issue of divided infringement has long been an issue in this case. As explained in other briefing, PureWick has repeatedly failed to identify any direct infringers, instead conflating various entities and accusing unrelated actors of direct infringement. Sage repeatedly raised the issue and asked PureWick to clarify a specific entity or person that performed each asserted step (*see, e.g.*, D.I. 204 at 11-12), but PureWick failed to do so. PureWick has never proven that any hospital or patient "individually" has taken every step of the asserted claims. If PureWick does in fact finally prove that is the case, then it should have no problem with this instruction; however it would be outside any allegation it has ever previously asserted in this litigation.

²² Plaintiff disagrees that this instruction is necessary because the issue of divided infringement is not relevant in this case. Plaintiff has never argued, nor does it plan to argue at trial, that more than one party is involved in practicing the steps of a claimed method. Rather, PureWick contends that Sage's customers, which include hospitals and patients, each individually directly infringe when they use the accused products.

acts of patients are attributable to hospitals, either because patients and hospitals have formed a joint enterprise or because hospitals directs or controls the acts of patients.

To prove that hospitals and patients have formed a joint enterprise, PureWick must prove four elements:

1. there was an agreement, either express or implied, between hospitals and patients;
2. they shared a common purpose;
3. each had a financial interest in that purpose; and
4. each had an equal right of control in the enterprise.

To prove that hospitals directed or controlled the acts of patients, PureWick must prove either that (1) patients are the agent of hospitals or are contractually obligated to hospitals to carry out the claimed steps, or (2) patients performed the claim step(s) in order to receive a benefit from hospitals and that hospitals established how or when the claim step(s) were performed.

H. DISPUTED: INDIRECT INFRINGEMENT: CONTRIBUTORY INFRINGEMENT

1. Plaintiff's Proposal²³

PureWick also asserts that Sage has contributed to infringement by third parties of the asserted claims of the '376, '989 and '407 patents by selling or offering for sale the PrimaFit and PrimoFit in the United States.

To establish contributory infringement, PureWick must prove that it is more likely than not that Sage had knowledge of the patent. PureWick must also prove that each of the following is more likely than not that:

1. A third-party directly infringes the claim;
2. Sage sold or offered for sale a component (e.g., PrimaFit) of the infringing combination, or an apparatus (e.g., PrimaFit) for use in the infringing method;
3. the component or apparatus is not a staple article or commodity of commerce capable of substantial non-infringing use;
4. the component or apparatus constitutes a material part of the claimed invention; and
5. Sage knew that the component or apparatus was especially made or adapted for use in an infringing product or method.

²³ Plaintiff's proposed language in this instruction is taken from the Court's Final Jury Instruction in *ArcherDX, LLC et al. v. Qiagen Sciences, LLC et al.*, No. 18-1019 (MN), D.I. 462 (Aug. 27, 2021). Sage contends that "PureWick deviates from *ArcherDX* including deleting portions of the instruction that related to the fact that it needs to prove both direct infringement and Sage's knowledge of the patent." This is wrong. PureWick's instruction clearly states that it must prove that Sage had knowledge of the patent, which is part of the second paragraph of PureWick's instruction, and that a third-party directly infringes the claim, which is the first item in the numbered list in PureWick's instruction.

2. Defendant's Proposal²⁴

Plaintiff also asserts that Sage has contributed to direct infringement by hospitals and patients of the asserted claims of the 376 and 989 patents by selling or offering for sale the PrimaFit and PrimoFit in the United States.

As with direct infringement, you must determine contributory infringement on a claim-by-claim basis.

To establish contributory infringement, the Plaintiff must prove by a preponderance of the evidence that hospitals or patients directly infringe the claim. As I mentioned, to find a direct infringement of a method claim, all steps of a claimed method must be performed by or attributable to a single entity. You must also find that the following are met to establish contributory infringement:

1. Sage sold or offered for sale a component of a product or an apparatus for use in in an infringing method during the time the 376 and 989 patents were in force;
2. the component or apparatus is not a staple article or commodity of commerce capable of substantial non-infringing use;
3. the component or apparatus constitutes a material part of the claimed invention;
4. Sage was aware of the particular patent at issue (376 patent, 989 patent); and
5. Sage knew that the component or apparatus was especially made or adapted for use as an infringement of the claim.

²⁴Defendant's instruction is adapted from the AIPLA Model Patent Jury Instructions § V at 3.10 (2019), which is more relevant to the issues in this case and addresses the divided infringement issue. While PureWick states that it follows *ArcherDX*, it does not. PureWick deviates from *ArcherDX* including deleting portions of the instruction that related to the fact that it needs to prove both direct infringement and Sage's knowledge of the patent. PureWick again deletes materials that would relate to the issue of divided infringement.

A “staple article or commodity of commerce capable of substantial non-infringing use” is something that has uses other than as a part or component of the patented product or in the patented method, and those other uses are not occasional, farfetched, impractical, experimental, or hypothetical.

I. WILLFUL INFRINGEMENT – ‘376 AND ‘989 PATENTS

In this case, PureWick contends that Sage infringed and, further, that Sage infringed the ‘376 and ‘989 patents willfully. If you find that Sage infringed a valid claim of the ‘376 and ‘989 patents, then you must also determine whether or not Sage’s infringement was willful.

To show that Sage’s infringement was willful, PureWick must prove by a preponderance of the evidence that Sage knew of PureWick’s patents at the time of the infringement and that the infringement was deliberate or intentional. You may not determine that the infringement was willful just because Sage was aware of the asserted patents and infringed them. Instead, you must also find that Sage deliberately or intentionally ignored or recklessly disregarded the patents.

In determining whether PureWick has proven that Sage’s infringement was willful, you must consider all of the facts and circumstances and assess Sage’s knowledge at the time the challenged conduct occurred. Facts that may be considered include, but are not limited, to:

1. whether Sage had knowledge of the ‘376 and ‘989 patents;
2. whether or not Sage acted consistently with the standards of behavior for its industry;
3. whether or not Sage intentionally copied a PureWick product that is covered by the asserted patents;
4. whether or not Sage reasonably believed it did not infringe or that the patents were invalid;
5. whether Sage knew, or should have known, that its conduct involved an unreasonable risk of infringement;
6. whether or not Sage made a good-faith effort to avoid infringing these patents, for example, whether Sage attempted to design around these patents; and
7. whether or not Sage tried to cover up its infringement.

If you determine that any infringement was willful, you may not allow that decision to affect the amount of any damages award you give for infringement.²⁵

²⁵ Adapted from the AIPLA Model Patent Jury Instructions § V at 3.10 (2019)

J. DISPUTED: INVALIDITY – GENERALLY

I will now instruct you on the rules you must follow in deciding whether or not Sage has proven that any asserted claims of the '376, '989, and '407 patents are invalid.

[Plaintiff's Proposal²⁶: A patent is presumed to be valid. In other words, it is presumed to have been properly granted by the PTO.²⁷ To prove that a claim of a patent is invalid, Sage must persuade you by clear and convincing evidence. That is, you must be left with a clear conviction that the claim is invalid.

You must determine whether each of the asserted claims is invalid on a claim-by-claim basis. For example, even if an independent claim is invalid, this does not mean that the dependent claims that depend from it are automatically invalid.

Sage contends that the asserted claims of the '376, '989, and '407 patents are invalid as anticipated and/or obvious. Sage also contends that claim 7 of the 407 Patent is invalid as indefinite and for failing to satisfy the written description requirement. I will provide additional instructions on each of those issues.]

[Defendant's Proposal:²⁸ Claims of an issued patent may be found to be invalid. Thus you must determine whether Sage has proven by clear and convincing evidence that each of the Asserted Claims are invalid.

²⁶ Authority: Plaintiff's proposed instruction closely tracks the Final Jury Instructions read to the jury in *ArcherDX, LLC et al. v. Qiagen Sciences, LLC et al.*, No. 18-1019 (MN), D.I. 462 (Aug. 27, 2021) with the exception of one sentence adapted from the AIPLA Model Instruction that was added to clarify that patents are entitled to a presumption of validity. Defendant's proposed instruction includes unnecessary and redundant information, which Defendant does not explain the significance or relevance of.

²⁷ Authority: Adapted from the AIPLA Model Patent Jury Instructions § II.A.ii (2019).

²⁸ Sage's proposal generally tracks *ArcherDX* but also includes additions from *Bio-Rad Laboratories, Inc. et al. v. 10X Genomics, Inc.*, No. 15-152-RGA, D.I. 470 (D. Del. Nov. 13, 2018)

Sage contends that the asserted claims of the 376, 989, and 407 patents are invalid as anticipated by the prior art and invalid as obvious in view of prior art and the knowledge of a person of ordinary skill in the art. Sage also contends that claim 7 of the 407 Patent is invalid as indefinite for failing to reasonably inform those skilled in the art what the patent claims cover. Sage further contends that claim 7 of the 407 patent is invalid because the patent specification fails to adequately describe the invention. I will provide additional instructions on each of those issues.

In making your determination as to whether a claim is invalid, you must consider each claim individually. Even if you find an independent claim is invalid, you must still individually determine whether any dependent claims that refer to an independent claim are invalid. However, if you find that a dependent claim is invalid, then you must find that the independent claim from which it depends is also invalid.]

The question of invalidity of a patent claim is determined from the perspective of a person of ordinary skill in the art in the field of the invention at the time of the invention date.

and the Federal Circuit Bar Association Model Patent Jury Instructions at § B.4.3 (2020), which has aspects that are more relevant to this case. Sage explains the invalidity defenses at a high level (as PureWick did for its infringement instructions but did not include here). Moreover, despite claiming to follow *ArcherDX*, PureWick's proposal deviates from *ArcherDX* in significant ways and omits important portions. For example, PureWick removes the portion that says "However, if you find the dependent claim is invalid, you must find that the independent claim from which it depends is also invalid." PureWick also includes a reference to the presumption of validity and discussion about the PTO doing its job properly. This proposal is prejudicial particularly given that the standard for validity is based on the presumption, giving the presumption undue weight.

K. DISPUTED: PERSON OF ORDINARY SKILL IN THE ART

As I mentioned, aspects of invalidity are determined from the perspective of a person of ordinary skill in the art in the field of the invention at the time of the invention date. Thus, prior art and other aspects of this case must be evaluated from the perspective of one of ordinary skill in the field of the invention as of the time of invention. You must determine the level of ordinary skill in the field of the invention.

When determining the level of ordinary skill in the art, you should consider all the evidence submitted by the parties, including evidence of:

1. the level of education and experience of persons actively working in the field at the time of invention, including the inventors;

2. the types of problems encountered in the art at the time of invention;

[Plaintiff's Proposal:²⁹

3. the sophistication of the technology in the art at the time of invention, including the rapidity with which innovations were made in the art at the time of invention.]

[Defendant's Proposal:³⁰

3. prior art solutions to those problems;

4. rapidity with which innovations are made; and

²⁹ Authority: Plaintiff's evidence relating to determining the level of ordinary skill in the art comes from § 7.3 of the AIPLA Model Patent Jury Instructions, section 7.3 (2019). Without citation or rationale, Defendant adds No. 3, which is not in the AIPLA model instructions, to its list and breaks Nos. 4 and 5 into two separate considerations when the AIPLA model instructions list both together as Plaintiff has done in its proposed instruction.

³⁰ These additional factors are found in the instruction in *E.I. Du Pont Nemours and Co. v. Unifrax I LLC*, No. 14-1250-RGA, D.I. 325; *Bio-Rad Laboratories, Inc. et al. v. 10X Genomics, Inc.*, No. 15-152-RGA, D.I. 470 (D. Del. Nov. 13, 2018). PureWick's instruction eliminates the factor of prior art solutions, which is relevant here, and combines rapidity and sophistication.

5. the sophistication of the technology in the art at the time of invention.]

L. PRIOR ART – GENERALLY

Under the patent laws, a patent is valid only if the invention claimed in the patent is new and not obvious in light of what came before. That which came before is referred to as “prior art.” Prior art includes items that were publicly known or that have been used or offered for sale, or references, such as publications or patents, that disclose the claimed invention or elements of the claimed invention. To be prior art, the item or reference must have been made, known, used, published, or patented either before the invention was made or more than one year before the earliest “priority date” of the patent application. I will instruct you about the effective priority date shortly.³¹

³¹ *E.I. Du Pont Nemours and Co. v. Unifrax I LLC*, No. 14-1250-RGA, D.I. 325; *Bio-Rad Labs., Inc. and the University of Chicago v. 10X Genomics, Inc.*, No. 15-cv-152-RGA, D.I. 470; The Federal Circuit Bar Association Model Patent Jury Instructions at § B.4.3 (2020).

M. EFFECTIVE FILING DATE OF '376 AND '989 PATENTS

1. Plaintiff's Proposal³²

The inventors of the '376 and '989 patents filed patent applications on March 19, 2014, November 25, 2014, and June 2, 2016, to which the '376 and '989 patents claim priority. You must determine whether the asserted claims of the '376 and '989 patents are sufficiently supported by one or more of these earlier applications. PureWick contends that the asserted claims of the '989 patent is entitled to the filing date of at least one of the March 19, 2014, November 25, 2014, or June 2, 2016 applications. PureWick contends that the '376 patent is also entitled to the filing date of at least one of the March 19, 2014, November 25, 2014, or June 2, 2016 applications, and also entitled to the filing date of the '989 patent. Sage contends that the asserted claims are not entitled to these earlier filing dates.

PureWick may rely on the filing date of their earlier patent applications to establish the effective filing date if any of those applications teaches one of ordinary skill in the art to make and use the claimed inventions of the '376 and '989 patents, and to do so without undue

³² Plaintiff's proposed instruction is taken from the Court's Final Jury Instruction in *ArcherDX, LLC et al. v. Qiagen Sciences, LLC et al.*, No. 18-1019 (MN), D.I. 462 (Aug. 27, 2021) with alterations made to account for the fact that, in this case, Plaintiff proposes three alternative priority dates. Defendant's proposed instruction mixes out-of-context statements from a number of different cases in a way that is both confusing and prejudicial. And although Defendant asserts that its instruction is taken from *Boston Scientific Corp. v. Edwards Lifesciences Corp.*, there are aspects that Sage has added without authority.

Further, Defendant's arguments that PureWick made changes to the proposed instructions "the day before these instructions were due" is irrelevant. Both parties made edits to the proposed instructions the day before they were due. PureWick has always contended that the '376 patent claims priority to the '989 patent and that the claims of the '376 patent, which are apparatus claims that are nearly identical in scope to the method claims of the '989 patent, are fully supported by the written description of the '989 patent specification. This fact should not even be in dispute.

experimentation. Additionally, the applications must disclose each and every element of the asserted claims of the '376 and '989 patents.

If you determine that PureWick has shown by a preponderance of the evidence that the asserted claims of the '376 and '989 patents are entitled to the filing date of any of the earlier applications, then Sage must prove by clear and convincing evidence that they are not.

If you find that PureWick is entitled to an effective filing date that is the same date as the filing date of one of the earlier applications, then the date of the earlier application is the effective filing date of the '376 and '989 patents for purposes of validity and the prior art]

2. Defendant's Proposal³³

A patent's "priority" date, which I will sometimes refer to as the "effective filing date," is a date that is used in assessing the validity of the patent. For example, a publication or public disclosure from after the patent's "priority date" is not "prior" art to that patent.³⁴

The priority date of an asserted patent claim can be based on the filing date of an earlier-filed patent application known as a "priority application."

In this case, the application for the 989 patent was filed on September 8, 2016, and the application for the 376 patent was filed on June 1, 2017. Here, PureWick contends that the asserted claims of the 376 and 989 patents are entitled to an earlier priority date based on the filing of March 2014, November 2014, or June 2016. Sage asserts that PureWick is not entitled to earlier dates.³⁵

³³ Sage's instruction is taken from *Boston Scientific Corp. v. Edwards Lifesciences Corp.*, No. 16-CV-275-JFB-SRF (D. Del.), D.I. 541 at Instruction No. 29, which involves several priority applications unlike the *ArcherDX* case and addresses other relevant issues; *see also* 35 U.S.C. § 120; *Medtronic CoreValve, LLC v. Edwards Lifesciences Corp.*, 741 F.3d 1359, 1363 (Fed. Cir. 2014); *Nat. Alternatives Int'l, Inc. v. Iancu*, 904 F.3d 1375, 1380 (Fed. Cir. 2018); *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1304 (Fed. Cir. 2008). Sage did, however, initially draft this instruction with the intent of adopting portions of PureWick's proposal including portions of *ArcherDX*.

PureWick's custom instruction is wrong for a multitude of reasons and oversimplifies (and thus legally confuses) the priority issues. First, it starts by assuming a fact that PureWick needs to prove, i.e., that the inventors have claimed priority to three particular applications. Second, it fails to advise the jury that the priority date is presumed to be the filing date. Third, it wrongly implies that PureWick can "mix and match" disclosure in three different applications when, in fact, PureWick must prove that a single application provides the requisite disclosure. Fourth, it fails to address the fact that the prior application must disclose the full scope of the invention, which is in the *Boston Scientific* instruction and well-established by *Power Oasis*. Fifth, PureWick presents the burdens in a confusing way without stating that PureWick bears the burden of proving priority but instead is written to shift the burden to Sage.

³⁴ This paragraph is taken from the instruction from *Boston Scientific Corp. v. Edwards Lifesciences Corp.*, No. 16-CV-275-JFB-SRF (D. Del.), D.I. 541 at Instruction No. 29.

³⁵ This paragraph tracked PureWick's original proposal, which has since changed. Sage notes that, the day before these instructions were due, PureWick changed its arguments and this instruction to contend that the '376 patent (filed in June 2017) is now entitled to a priority date of

For the 376 or 989 Patent to obtain the benefit an earlier priority date, PureWick must show, by a preponderance of the evidence, that a prior application enables and provides sufficient written description of every element of the claim. In deciding whether the asserted claims are entitled to the priority date of an earlier patent application (in this case either March 2014, November 2014, or June 2016 application), you must consider the descriptions of each of those patent application from the viewpoint of a person of ordinary skill in the art of the patent when the application was filed. The asserted claims of the 376 and 989 patents are entitled to an earlier priority date if you find, by a preponderance of the evidence, at that time, a person of ordinary skill reading the single earlier application would have recognized that it describes the full scope of the claimed invention as set forth in the patent claims and that the inventor actually possessed the full scope by the filing date of that application. In addition, the description in the earlier application must contain enough information to permit a person of ordinary skill in the field to make and use the full scope of the claimed invention without undue experimentation.³⁶

In determining whether a single application provides an adequate disclosure, you may not combine embodiments or disclosures in the March 2014, November 2014, or June 2016 application; rather the disclosure must be present in a single prior application for PureWick to

the ‘989 patent (filed in September 2016). PureWick’s expert offered no opinion on whether the specification of the ‘989 patent supported the full scope of the claims of the ‘376 patent. (See D.I. 210, Ex. 33 at Paras. 1193-1195.)

³⁶ This paragraph tracks the *Boston Scientific* instruction with reference to the applications in this case.

claim priority to that application. Additionally, you may give deference to any determinations by the Patent Office regarding the effective priority date of a particular claim.³⁷

To establish entitlement to the earlier priority date, PureWick must present enough evidence as I have described above. However, the ultimate burden of proving invalidity of the asserted patent claims remains with Sage.³⁸

You will be asked to determine whether PureWick has proven by a preponderance of the evidence that it can claim priority to an earlier application and, if so, whether the priority date of the Asserted Claims of the 376 and 989 patents are March 2014, November 2014, or June 2016. If you find that Plaintiff is not entitled to claim priority to an earlier application, the effective filing date of the 376 patent and the 989 patent is the date that those patents were filed. The applications for the 376 was filed on June 1, 2017 and the 989 September 8, 2016, respectively. If you find that Plaintiff is not entitled to claim priority to an earlier application, the effective filing date of the 376 patent is June 1, 2017, and the effective filing date of the 989 Patent is September 8, 2016.

N. DISPUTED: INVALIDITY: ANTICIPATION

1. Plaintiff's Proposal³⁹

An invention must be new to be entitled to patent protection under the U.S. patent laws. If a device or process has been previously invented and disclosed to the public, then it is not new,

³⁷ This paragraph addresses PureWick's implication that one can mix and match from various applications. *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1304 (Fed. Cir. 2008).

³⁸ This paragraph is taken from the *Boston Scientific* instruction.

³⁹ Plaintiff's proposed instruction is adapted from the Court's Final Jury Instruction in *ArcherDX, LLC et al. v. Qiagen Sciences, LLC et al.*, No. 18-1019 (MN), D.I. 462 (Aug. 27, 2021) with alterations taken from the Final Jury Instructions read to the jury in *TrustID, Inc. v. Next Caller Inc.*, No. 18-172 (MN), D.I. 295 (July 16, 2021). Those alterations are for the purpose of clarifying that anticipation can be based on different types of prior art (e.g., a prior publication,

and therefore the claimed invention is “anticipated” by the prior art. To prove anticipation, Sage must prove that the claimed invention is not new by clear and convincing evidence.

In this case, Sage contends that the asserted claims of the ’376, ’989, and ’407 patents are anticipated. You must determine what is the prior art that may be considered in determining whether the asserted claims of the ’376, ’989, and ’407 patents are new or anticipated.

Anticipation must be determined on a claim-by-claim basis. In order for a patent claim to be anticipated by the prior art, each and every limitation of the claim must be present within a single item of prior art, whether that prior art is a publication, a prior patent, a prior invention, a prior public use or sale, or some other item of prior art. You may not combine two or more items of prior art to find anticipation.

In determining whether every one of the elements of the claimed invention is found in the prior publications and patents identified by Sage, you should consider what a person of ordinary skill in the art would have understood from his or her review of the particular devices, publications and patents. A printed publication or patent will not anticipate a patent claim unless it contains a description of the invention covered by the patent claims that is sufficiently detailed that it teaches a skilled person how to make and use the invention without undue experimentation.

patent, public use or sale). Defendant’s instruction mixes irrelevant statements from a number of different cases, which is both confusing and prejudicial.

Defendants have also added an instruction that “While you may not combine two or more items of prior art to find anticipation, you may find a single prior art reference anticipates if it incorporates by reference another prior art reference,” which is not found in any sample jury instruction cited by Defendant and does not accurately state the law. In particular, Defendants omit that “[t]o incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents.” *Advanced Display Sys., Inc. v. Kent State University*, 212 F.3d 1272, 1283 (Fed. Cir. 2000). Moreover, “[w]hether and to what extent material has been incorporated by reference into a host document is a question of law” and “instructing the jury to make that determination [is] legal error.” *Id.*

In deciding whether or not a single item of prior art anticipates a patent claim, you should consider what is expressly stated or present in the item of prior art and also that which is inherently present. Something is inherent in an item of prior art if it is always present in the prior art or always results from the practice of the prior art and if a skilled person would understand that to be the case.⁴⁰

2. Defendant's Proposal⁴¹

In this case, Sage contends that the asserted claims of the 376, 989, and 407 patents are not new and thus are invalid as “anticipated.” An invention must be new to be entitled to patent protection under the U.S. patent laws. If a device or process has been previously invented, made, used, or disclosed to the public before, then it is not new, and therefore the claimed invention is “anticipated” by the prior art. To prove anticipation, Sage must prove that the claimed inventions are not new by clear and convincing evidence. Anticipation must be determined on a claim-by-claim basis. To anticipate a patent claim, each element in the claim must be present in a single item of prior art, whether that prior art is a publication, a prior patent, a prior invention, a prior public use or sale, or some other item of prior art. While you may not combine two or more items

⁴⁰ This paragraph is taken from the Final Jury Instructions read to the jury in *TrustID, Inc. v. Next Caller Inc.*, No. 18-172 (MN), D.I. 295 (July 16, 2021). Defendant's argument that PureWick added this portion of the instruction one day before the instructions were due is irrelevant. Both parties made edits to the proposed instructions the day before they were due in an effort to compromise and present agreed to instructions that accurately state the law that is relevant to this case. Defendant does not dispute that PureWick's instruction on inherency is correct.

⁴¹ As explained herein, this instruction tracks *ArcherDX, LLC et al. v. Qiagen Sciences, LLC et al.*, No. 18-1019 (MN), D.I. 462 (Aug. 27, 2021) and includes items that Plaintiff omitted or removes items that Plaintiff added unnecessarily. It also addresses the issue of incorporation by reference as explained herein.

Sage further notes that PureWick added an instruction on inherency to its proposal one day before the instructions were due (despite earlier claiming that such instructions were unnecessary). Sage addresses inherency using the AIPLA instruction in Instruction O below.

of prior art to find anticipation, you may find a single prior art reference anticipates if it incorporates by reference another prior art reference.⁴² In determining whether every one of the elements of the claimed invention is found in the prior publications, patents, and devices identified by Sage, you should consider what a person of ordinary skill in the art would have understood from his or her review of those items. The same element of the prior art may satisfy more than one element of a patent claim.⁴³ If you find that any of the Asserted Claims was anticipated by a single item of prior art, then that claim is invalid.

⁴² Here, Defendant continues to track *ArcherDX*. Defendant's proposal clarifies that, while two or more references cannot be combined for anticipation, anticipation can be present if one reference incorporates by reference another document, which is relevant in this case. *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1329 (Fed. Cir. 2001) ("When a document is 'incorporated by reference' into a host document, such as a patent, the referenced document becomes effectively part of the host document as if it were explicitly contained therein."). PureWick ignores this issue.

⁴³ PureWick added this sentence for infringement in Instruction D above; thus, if the statement is included for infringement, it should also be included for anticipation.

O. DISPUTED: INVALIDITY: ANTICIPATION (INHERENCY)

Defendant's Proposal:^{44, 45} In determining whether a single item of prior art anticipates a patent claim, you should take into consideration not only what is expressly disclosed in the particular prior art reference but also what is inherently present or disclosed in that prior art or inherently results from its practice. Prior art inherently anticipates a patent claim if the missing element or feature would necessarily result from what the single item of prior art teaches to persons of ordinary skill in the art. A party claiming inherent anticipation must prove by clear and convincing evidence that the allegedly inherent element necessarily is present. Evidence outside of the prior art reference itself may be used to show that elements that are not expressly disclosed in the reference are inherent in it. In order to be inherent, the feature that is alleged to have been inherent must necessarily have existed in the prior art reference. The fact that it was likely is not sufficient. It is not required, however, that persons of ordinary skill actually recognize or appreciate the inherent disclosure at the time the prior art was first known or used. Thus, the prior use of the patented invention that was unrecognized and unappreciated can still be an invalidating anticipation, provided the allegedly inherent feature was necessarily present in the reference.

⁴⁴ Sage proposes an instruction relating to the issue of inherency taken from AIPLA Model Patent Jury Instructions, § V.6 (2019). As noted above, PureWick did not include a counter-instruction on that issue until the day before instructions were due. PureWick never clarified what was wrong with Sage's proposal, which tracks the AIPLA model.

⁴⁵ PureWick disagrees that a standalone instruction on inherency is necessary. Indeed, the AIPLA model instructions include an inherency instruction within the anticipation instruction. Thus, PureWick has included a clearer and more succinct instruction on inherency taken from the Final Jury Instructions read to the jury in *TrustID, Inc. v. Next Caller Inc.*, No. 18-172 (MN), D.I. 295 (July 16, 2021) within its proposed instruction on anticipation.

P. INVALIDITY: PRINTED PUBLICATIONS AND PRIOR PATENTS

Sage contends that the asserted claims of the 376,989, and 407 patents are invalid because the invention defined in those claims were described in a printed publication or were patented in the United States or a foreign country before the effective filing date of the 376,989, and 407 patents.

A patent claim is invalid if the invention defined by those claims was described in a publication or patent printed before the effective filing date of the patents-in-suit.⁴⁶

⁴⁶ Adapted from AIPLA Model Patent Jury Instructions, § V.6.5 (2019); *see* The Federal Circuit Bar Association Model Patent Jury Instructions § B.4.3a-2, 3 (2020).

Q. DISPUTED: INVALIDITY: PRIOR PUBLIC KNOWLEDGE AND USE

Sage contends that the asserted claims of the 376, 989, and 407 patents are invalid because the claimed inventions were available to the public and in public use anywhere in the world before the effective filing date of the 376, 989, and 407 patents.

A patent claim is invalid if the claimed invention was available to the public and was in public use before the effective filing date of the claimed invention.

[Plaintiff's Additional Proposal:^{47, 48} However, a patent claim will not be invalid if the claimed invention was publicly made available or used by the inventor(s), or someone who obtained the claimed invention from the inventors, one (1) year or less before the effective filing date of the claimed invention.] An invention was in public use if the claimed invention was accessible to the public or commercially exploited anywhere in the world. Factors relevant to determining whether a use was public include the nature of the activity that occurred in public;

⁴⁷ This instruction is necessary, as recognized by the AIPLA. *See* AIPLA Model Patent Jury Instructions, § V.6.1.2(2019) (If there is a factual issue to be resolved by the jury as to whether the public availability is the result of a disclosure made within one year or less of the effective filing date by the inventor or a joint inventor . . . then the jury should be instructed here as to exceptions under § 102(b) and (c) as needed.”). Though the AIPLA does not include this instruction within the “Prior Public Use” instruction, it includes a similar instruction within the “Prior Art Defined (AIA)” instruction. *See* AIPLA Model Patent Jury Instructions, § V.5.0.2 (2019). To avoid confusing the jury, Plaintiff has included this instruction on “Exceptions to Prior Art,” where it is most relevant. Without this additional sentence, the statement that “A patent claim is invalid if the claimed invention was available to the public and was in public use before the effective filing date of the claimed invention” standing alone is incorrect.

Defendant’s argument that “there is no dispute about disclosures made less than a year before the filing date” is incorrect. Defendant is relying on an alleged prior use or sale by PureWick that, depending upon the priority dates of the patents-in-suit, may be less than a year before the effective filing dates.

⁴⁸ Defendant contends that this additional proposal is not in the AIPLA model on this issue and is not necessary. Plaintiff is apparently mixing and matching instructions and creating confusion with unnecessary instructions. Here there is no dispute about disclosures made less than a year before the filing date; the prior art at issue here relates to disclosures more than a year before the filing dates.

public access to the use; confidentiality obligations imposed upon observers; commercial exploitation; and the circumstances surrounding any testing and experimentation. An invention **[Plaintiff's proposal: may be; Defendant's proposal:^{49, 50} is]** publicly used if it is used by the inventor or by a person who is not under any limitation, restriction, or obligation of secrecy to the inventor. The absence of affirmative steps to conceal the use of the invention is evidence of a public use. However, secret use by a third party is not public, unless members of the public or employees of the third party have access to the invention.

To be a public use, the invention also must have been ready for patenting at the time of the alleged public use. I will explain this concept shortly.

⁴⁹ Defendant tracks the AIPLA language. In contrast, Plaintiff's proposal is incorrect and confusing, as it expressly states that an invention "may be publicly" used, which suggests that such use is permissible (and not invalidating). PureWick changes the AIPLA instruction and its arguments reference experimental use; however, there is an instruction on experimental use forthcoming (Instruction S).

⁵⁰ Plaintiff states that Defendant's proposed language fails to account for the fact that there are exceptions to public use, including experimental use.

R. DISPUTED: INVALIDITY – ON SALE BAR

Sage contends that the asserted claims of the 376 and 989 patents are invalid because the inventions defined in those claims were on sale before the effective filing date of those patents.

The patent claims are invalid if, more than one year before the effective filing dates, an embodiment of the claimed invention was both (1) the subject of a commercial sale [**Defendant's Additional Proposal:** or offer for sale] and (2) ready for patenting.

[**Defendant's Additional Proposal:**^{51, 52} A commercial offer for sale was made if another party could make a binding contract by simply accepting the offer. An invention was subject to an offer for sale if the claimed invention was embodied in an actual product and that product was commercially sold or offered for sale, even if it was done confidentially. It is not required that a sale was made.]

The invention also must have been ready for patenting at the time of the sale or offer for sale. The claimed invention is ready for patenting when there is reason to believe it would work for its intended purpose. An invention is ready for patenting either when it is reduced to practice or when the inventor has prepared drawings or other descriptions of the invention sufficient to allow a person of ordinary skill in the art to make or use the invention. An invention is reduced to practice when it has been (1) constructed or performed within the scope of the patent claims, and (2) determined that it works for its intended purpose.

⁵¹ This entire instruction, including this paragraph, follows AIPLA Model Patent Jury Instructions, §V.6.3 (2019). Contrary to Plaintiff's statement, Sage alleges the claims are invalid based on prior sales and offers for sale including available marketing materials. Indeed, this was part of Sage's motion for summary judgment of invalidity. (D.I. 204 at 13-21.)

⁵² Plaintiff does not believe this instruction is necessary because Defendant has never contended that the patents are invalid based on an alleged offer for sale.

S. DISPUTED: EXPERIMENTAL USE

[**Plaintiff's Proposal:**⁵³ PureWick denies that the inventions defined by the asserted claims of the '376 and '989 patents were available to the public or the subject of a commercial sale one year before the effective filing date. PureWick also contends that any use of the claimed inventions one year before the effective filing date was experimental; **Defendant's Proposal:**⁵⁴ PureWick contends that any prior public use and sale of the inventions should not be considered a prior public use of the invention or placing the invention on sale because that use and sale were experimental.]

The law recognizes that the inventor must be given the opportunity to develop the invention through experimentation. Certain activities are experimental if they are a legitimate effort to test claimed features of the invention or to determine if the invention will work for its intended purpose. So long as the primary purpose is experimentation, it does not matter that the public used the invention or that the inventor incidentally derived profit from it.

[**Defendant's Additional Proposal:**^{55, 56} Only experimentation by or under the control of the inventor of the patent qualifies for this exception. Experimentation by third parties, for its own

⁵³ Plaintiff's proposed instruction accurately states the dispute, whereas Defendants' proposed instruction is prejudicial because it assumes there has been a prior use or sale, e.g., "that *the prior public use and sale of the inventions* should not be considered a prior public use."

⁵⁴ Defendant's instruction tracks the AIPLA Model Patent Jury Instruction V.6.4. (2019). PureWick's first sentence deviates from the model and is argumentative.

⁵⁵ PureWick omits this portion from the AIPLA Model Patent Jury Instruction V.6.4. (2019). It should be included. PureWick now claims that the AIPLA instruction—that it selected in the first instance—is legally inaccurate. PureWick is not accurately stating the law or describing the full scope of the *Barry* case, which discusses numerous factors.

⁵⁶ PureWick omits this portion from the AIPLA because it is not an accurate statement of the law. The Federal Circuit laid out the law for experimental use in *Barry v. Medtronic, Inc.*, 914 F.3d 1310, 1328 (Fed. Cir. 2019), and it never mentioned a requirement that experimentation be for the ambiguous "purpose of technological improvement." It said, instead, that "[a] use may be experimental if its purpose is: '(1) [to] test claimed features of the invention or (2) to determine whether an invention will work for its intended purpose—itself a requirement of patentability.'"

purposes, does not. The experimentation must relate to the features of the claimed invention, and it must be for the purpose of technological improvement, not commercial exploitation. If any commercial exploitation does occur, it must be merely incidental to the primary purpose of experimentation. A test done primarily for marketing, and only incidentally for technological improvement, is not an experimental use.]

It is PureWick’s burden to come forward with evidence showing that the purpose of the prior public use or prior sale was experimental. [**Plaintiff’s Proposal:**⁵⁷ You may find that there has been no prior public use of the invention or that the invention was not placed on sale if the evidence provided by PureWick regarding the experimental use prevents Sage from meeting its burden of establishing that it is highly probable that there was a prior public use or sale.; **Defendant’s Proposal:**⁵⁸ If the evidence of the experimental use produced by PureWick is strong enough that you find that Defendant has not met its burden of establishing a prior public use and prior sale by clear and convincing evidence, you may find that use or sale does not constitute a prior public use of the invention and placing the invention on sale].

Id. (quoting *Polara Eng’g Inc v. Campbell Co.*, 894 F.3d 1339, 1348 (Fed. Cir. 2018)). Additionally, the statement that “[o]nly experimentation by or under the control of the inventor of the patent qualifies for this exception” conflicts with the Federal Circuit’s statement in *Barry* that there are “a host of factors that can be relevant to assessing whether a use is experimental, including: . . . (2) the amount of control over the experiment retained by the inventor,” *id.*, and that “[e]xperimental use is a question of law to be analyzed ***based on the totality of the surrounding circumstances.***” *Id.* (quoting *Petrolite Corp. v. Baker Hughes Inc.*, 96 F.3d 1423, 1426 (Fed. Cir. 1996)) (emphasis added).

⁵⁷ PureWick’s proposal is adapted from the AIPLA model. *See* AIPLA Model Patent Jury Instruction V.6.4. (third paragraph) (2019). PureWick’s changes to the AIPLA Model language are only to put the instruction regarding the burden in layman’s terms and to clear up the confusion regarding the meaning of “strong enough” in the AIPLA model instructions.

⁵⁸ PureWick’s language deviates from the AIPLA model while Sage’s proposal tracks the model. PureWick’s purported change to assist “laymen” is not helpful.

T. DISPUTED: INVALIDITY: OBVIOUSNESS (GENERALLY)

Even though an invention has not been identically disclosed or described before it was made by an inventor, in order to be patentable, the invention must also not have been obvious to a person of ordinary skill in the field of technology of the patent at the time the invention was made. Sage contends the asserted claims of the 376, 989, and 407 are invalid as obvious. Sage may establish that a patent claim is invalid by proving, by clear and convincing evidence, that the claimed invention would have been obvious to persons having ordinary skill in the pertinent art at the time of the invention of the patents-in-suit.

In determining whether the claimed invention was obvious, consider each claim separately, but understand that if a dependent claim is obvious, then the claims from which it depends are necessarily obvious as well.

In determining whether an asserted claim is obvious, you must consider the level of ordinary skill in the pertinent field that someone would have had at the time the invention was made, the scope and content of the prior art, the differences between the prior art and the claimed invention, and, if present, objective evidence or secondary considerations, which I will describe shortly.

The person of ordinary skill in the art is presumed to be aware of all of the pertinent prior art. A person of ordinary skill is also a person of ordinary creativity, not an automaton. Do not use hindsight; consider only what was known at the time of the inventions.

[Defendant's Additional Proposal: ⁵⁹ Common sense teaches, however, that familiar items may have obvious uses beyond their primary purposes, and in many cases a person of

⁵⁹ Defendant notes that Plaintiff removed this paragraph that was part of the *ArcherDX* instruction. It should be included.

ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle. When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious.]

[Plaintiff's Proposal:⁶⁰ Keep in mind that the existence of each and every element of the claimed invention in the prior art does not necessarily prove obviousness.; **Defendant's Proposal:**⁶¹ You must also consider the differences, if any, between the prior art and the claimed inventions. Importantly, a claim is not proved obvious merely by demonstrating that each of the elements was independently known in the prior art.] Most, if not all, inventions rely on building blocks of prior art. In considering whether a claimed invention is obvious, you should consider whether, at the relevant time, there was a reason that would have prompted a person having ordinary skill in the field of the invention to combine the known elements in the prior art in a way the claimed invention does. **[Defendant's Additional Proposal:**⁶² The motivation to modify the prior art to arrive at the claimed invention need not be the same motivation that the inventor had.] You may take into account such factors as (1) whether the claimed invention was merely the

⁶⁰ Plaintiff's proposed instruction is taken directly from the Federal Circuit Bar Association Model Patent Jury Instructions § B.4.3c (2020). Defendant's proposed instruction, by contrast, combines statements from numerous different cases in a way that is confusing and prejudicial. Additionally, Defendant's instructions unnecessarily recite secondary considerations that neither party has raised in this case.

⁶¹ Defendant's proposal for this first sentence is from *Bio-Rad Laboratories, Inc. et al. v. 10X Genomics, Inc.*, No. 15-152-RGA, D.I. 470 (D. Del. Nov. 13, 2018).

⁶² Defendant's additional proposal was in *Bio-Rad Laboratories, Inc. et al. v. 10X Genomics, Inc.*, No. 15-152-RGA, D.I. 470 (D. Del. Nov. 13, 2018).

predictable result of using prior art elements according to their known function(s); (2) whether the claimed invention provides an obvious solution to a known problem in the relevant field; (3) whether the prior art teaches or suggests the desirability of combining elements claimed in the invention; (4) whether the prior art teaches away from combining elements in the claimed invention; (5) whether it would have been obvious to try the combinations of elements, such as when there is a design incentive or market pressure to solve a problem and there are a finite number of identified, predictable solutions. To find it rendered the claimed invention obvious, you must find that the prior art provided a reasonable expectation of success. **[Plaintiff's Additional Proposal:^{63, 64} Obvious to try is not sufficient in unpredictable technologies.]**

[Defendant's Additional Proposal:⁶⁵ In determining whether a reference "teaches away" from the invention, you must keep in mind that a reference also does not teach away if it merely expresses a general preference. A reference does not teach away if it does not criticize, discredit, or otherwise discourage investigation into the invention claimed.]

⁶³ This sentence is taken directly from the Federal Circuit Bar Association Model Patent Jury Instructions § B.4.3c (2020).

⁶⁴ Plaintiff has not provided any explanation for why this sentence was added to the *ArcherDx* instruction.

⁶⁵ Defendant contends that an instruction on "teaching away" is necessary due to the errors made by PureWick's expert on this issue. In ruling on Sage's *Daubert* motion on teaching away, the Court stated that "Then we have the teaching away issue. That was one where I think I mentioned at the last hearing, there might be something in one of those . . . to the extent you want to object at trial, you can." (D.I. 279 at 55:9-15.) *See Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 739 (Fed. Cir. 2013); *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1327 (Fed. Cir. 2009).

U. DISPUTED: INVALIDITY: OBVIOUSNESS (SECONDARY CONSIDERATIONS)

1. Plaintiff's Proposal⁶⁶

In determining whether the claimed invention is obvious, you should take into account any objective evidence (sometimes called “secondary considerations”) that may shed light on whether or not the claimed invention is obvious, such as:

- a. Whether the claimed invention was commercially successful as a result of the merits of the claimed invention (rather than the result of design needs or market-pressure advertising or similar activities);
- b. Whether the claimed invention satisfied a long-felt need;
- c. Whether others had tried and failed to make the claimed invention;
- d. Whether others copied the claimed invention;
- f. Whether the claimed invention achieved unexpected results;
- g. Whether others in the field praised the claimed invention; and
- h. Whether persons having ordinary skill in the art of the invention expressed surprise or disbelief regarding the claimed invention;

In determining whether the claimed invention was obvious, consider each claim separately, but understand that if a dependent claim is obvious, then the claims from which it depends are necessarily obvious as well.

⁶⁶ Plaintiff's proposed instruction is taken directly from the Federal Circuit Bar Association Model Patent Jury Instructions § B.4.3c (2020). Defendant's proposed instruction, by contrast, combines statements from numerous different cases in a way that is confusing and prejudicial. Additionally, Defendant's instructions unnecessarily recite secondary considerations that neither party has raised in this case.

2. Defendant's Proposal⁶⁷

In determining whether the claimed invention is obvious, you should take into account any objective evidence (sometimes called “secondary considerations”) that may shed light on whether or not the claimed invention is obvious, such as:

1. whether the claimed invention was commercially successful as a result of the merits of the claimed invention (rather than the result of design needs or market-pressure, advertising, or similar activities);
2. whether others had tried and failed to make the claimed invention;
3. whether others copied the claimed invention;
4. whether the claimed invention satisfied a long-felt need that was solved by the invention;
5. whether others invented the claimed invention at roughly the same time;
6. whether there were changes or related technologies or market needs contemporaneous with the claimed invention;
7. whether others in the field praised the claimed invention;
8. whether persons having ordinary skill in the art of the invention expressed surprise or disbelief regarding the claimed invention;
9. whether the invention achieved unexpected results;
10. whether others sought or obtained rights to the patent from the patent holder; and
11. whether the inventor proceeded contrary to accepted wisdom in the field.

⁶⁷ Contrary to PureWick's assertions, Defendant's proposal follows *ArcherDx* and does not eliminate secondary considerations that must be considered. Sage also follows the order of *ArcherDx* rather than placing them in a particularly preferred order. Contrary to PureWick's contentions, all the factors are at issue at least because Sage's experts considered them, as they are required to in an obviousness determination.

These factors should be considered along with all the other evidence in the case in determining whether the asserted claims would have been obvious. In considering this kind of evidence, you should consider whether the secondary consideration was attributable to the features of the asserted claims as opposed to features already found in the prior art. In other words, there must be a connection between the evidence showing any of these factors and the merits of the claimed inventions if this evidence is to be given weight by you in arriving at your conclusion on the obviousness issue. For example, if commercial success is due to advertising, promotion, salesmanship or the like, or is due to features of the products other than those claimed in the patents in suit, then any commercial success may have no relation to the issue of obviousness.⁶⁸

⁶⁸ Sage proposes the last two sentences, which relate to nexus, and are from *Bio-Rad Laboratories, Inc. et al. v. 10X Genomics, Inc.*, No. 15-152-RGA, D.I. 470 (D. Del. Nov. 13, 2018).

V. DISPUTED: INVALIDITY: INDEFINITENESS

Defendant's Proposal:^{69, 70} The patent laws have requirements for the way in which patent claims are written. Patent claims must be sufficiently clear that a person of ordinary skill in the art reading them is able to determine what the claims cover and what they do not cover. If a patent claim does not meet this requirement, then the claim is said to be indefinite, and the claim is invalid.

In this case, Sage contends that claim 7 of the 407 Patent is invalid because the language of the claims is indefinite.

The amount of detail required for a claim to be definite depends on the particular invention, the prior art, and the description of the invention contained in the patent. A claim may be indefinite, for example, if it recites both an apparatus and a method of using that apparatus. To be definite, a patent claim, when read along with the rest of the patent, must reasonably inform those skilled in the art what the patent claims cover. Simply because claim language may not be precise does not automatically mean that the claim is indefinite.

⁶⁹ Defendant's instruction is from *ArcherDX, LLC et al. v. Qiagen Sciences, LLC et al.*, No. 18-1019 (MN), D.I. 462 (Aug. 27, 2021); see also *IPXL Holdings, L.L.C. v. Amazon.com, Inc.*, 430 F.3d 1377, 1384 (Fed. Cir. 2005). As explained above in Instruction II.A, the issue of indefiniteness remains undecided after summary judgment and is appropriate for jury determination. *See id.*; see also *Pac. Biosciences of CA, Inc. v. Oxford Nanopore Techs., Inc.*, No. CV 17-1353-LPS-CJB, 2020 WL 4699049, at *11 (D. Del. Aug. 13, 2020), *aff'd*, 996 F.3d 1342 (Fed. Cir. 2021) (appropriate to put indefiniteness before the jury); *Bombardier Recreational Prod. Inc. v. Arctic Cat Inc.*, 785 F. App'x 858, 866 (Fed. Cir. 2019); *Green Edge Enters., LLC v. Rubber Mulch Etc., LLC*, 620 F.3d 1287, 1299 (Fed. Cir. 2010) (Indefiniteness is a question of law based on underlying fact determinations that are appropriate for the jury).

⁷⁰ It is Plaintiff's position that indefiniteness is a question of law and thus should be decided by the Court, not the jury. *See Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1341 (Fed. Cir. 2015) ("Indefiniteness is a question of law.").

If you find that a person of ordinary skill in the art would not understand with reasonable certainty what is, and what is not, covered by claim 7 of the 407 patent, you must find that claim invalid. The issue of indefiniteness is assessed on a claim-by-claim basis.

W. DISPUTED: INVALIDITY: WRITTEN DESCRIPTION REQUIREMENT

A patent must contain a written description of the invention claimed in the patent. The written description requirement helps ensure that the patent applicant actually invented the full scope of the claimed subject matter. To satisfy the written description requirement, the patent specification must describe each and every limitation of a patent claim, in sufficient detail, although the exact words found in the claim need not be used.

[Plaintiff's Proposal]⁷¹: Sage contends that claim 7 of the 407 patent is invalid because the specification of those patents do not contain an adequate written description of those claims. Sage bears the burden of establishing by clear and convincing evidence that the specification of each of those patents fails to provide adequate written description support for those claims.

When determining whether the specification discloses the invention, the claim must be viewed as a whole.

The written description requirement is satisfied if persons of ordinary skill in the field of the invention would recognize, from reading the patent specification, that the inventor possessed the subject matter finally claimed in the patent. The written-description requirement is satisfied if the specification shows that the inventor possessed his or her invention as of the effective filing date of the claimed invention, even though the claims may have been changed or new claims added since that time. It is unnecessary to spell out every detail of the invention in the specification, and specific examples are not required; but enough must be included in the specification to convince

⁷¹ Plaintiff's proposed instruction is taken directly from the Court's Final Jury Instructions read to the jury in *ArcherDX, LLC et al. v. Qiagen Sciences, LLC et al.*, No. 18-1019 (MN), D.I. 462 (Aug. 27, 2021). Defendant's proposed instruction mixes statements from multiple sources in a way that is confusing and prejudicial. Defendant's proposed instruction also includes information that is irrelevant and redundant of other the information provided in earlier instructions.

persons of ordinary skill in the art that the inventor possessed the full scope of the invention. In evaluating whether the specification has provided an adequate written description, you may consider such factors as:

1. the nature and scope of the patent claims;
2. the complexity, predictability, and maturity of the technology at issue;
3. the existing knowledge in the relevant field; and
4. the scope and content of the prior art.

The issue of written description is decided on a claim-by-claim basis, not as to the entire patent or groups of claims.

If you find that Sage has proven by clear and convincing evidence that the patent specification does not contain adequate written description for the invention recited in claim 7 of the '407 patent, then you must find that the claim is invalid.]

[Defendant's Proposal⁷²: As we discussed, PureWick contends that three earlier patent application (the March 2014, November 2014, and June 2016 applications) provide written description support for the claims of the 376 and 989 patents. PureWick bears the burden of establishing by a preponderance of the evidence that the specification of a single application provides written description support for the claims.

Sage further contends that claim 7 of the 407 patent is invalid because the specification of those patents do not contain an adequate written description of those claims. Sage bears the burden

⁷² Defendant's instruction is taken from the Federal Circuit Bar Association Model Patent Jury Instructions § B.4.2 at 4.2a (2020); *see also Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 37 (1997). PureWick's instruction is incomplete because it does not address the written description requirement as it relates to its own burden of proving priority and whether the prior applications satisfy the written description requirement vis-à-vis the claims. Sage's proposal appropriately addresses both issues. PureWick's proposal is also confusing because, while purporting to only relate to Claim 7 of the 407 patent, it references multiple claims at once.

of establishing by clear and convincing evidence that the specification of each of those patents fails to provide adequate written description support for those claims.

In deciding whether the patent satisfies this written description requirement, you must consider the description from the viewpoint of a person having ordinary skill in the art when the application was filed. The written description requirement is satisfied if a person having ordinary skill reading the original patent application would have recognized that it describes the full scope of the claimed invention as it is finally claimed in the issued patent and that the inventor actually possessed that full scope of the filing date of the original application.

The written description requirement may be satisfied by any combination of the words, structures, figures, diagrams, formulas, etc., contained in the patent application. The full scope of a claim or any particular requirement in a claim need not be expressly disclosed in the original patent application if a person having ordinary skill in the field of technology of the patent at the time of filing would have understood that the full scope or missing requirement is in the written description in the patent application.

The issue of written description is assessed on a claim-by-claim basis.

As I discussed above, you must consider whether the March 2014, November 2014, and June 2016 applications provide written description support for the asserted claims of the 376 and 989 patents to determine the effective priority date of the claims. Additionally, if you find that Sage has proven by clear and convincing evidence that claim 7 of the 407 patent does not contain adequate written description for the inventions recited in those claims, then you must find that the claim is invalid.]

III. DAMAGES

A. DAMAGES – GENERALLY

I will next instruct you on damages. You must not take these instructions as implying my view about which party is entitled to your verdict in this case. Instructions regarding the measure of damages are given for your guidance in the event you find in favor of PureWick in the case in accordance with the other instructions.

I previously told you which products and methods PureWick accuses of infringing each of the patents. If you find that the PrimaFit infringes any of the asserted claims of the 376 patent or that the use of PrimaFit infringes any of asserted claims of the '989 patent, or if the PrimoFit infringes any of the asserted claims of the 407 patent, and that those infringed claims are not invalid, you must determine the amount of damages to be awarded to PureWick for the infringement. On the other hand, if you find that each of the asserted patent claims is invalid or is not infringed, then PureWick is not entitled to any damages and you should not consider damages in your deliberations.

PureWick must prove each element of its damages – including the amount of the damages – by a preponderance of the evidence, which means more likely than not.

If proven by Plaintiff, damages must be in an amount adequate to compensate PureWick for the infringement. The purpose of a damages award is to put PureWick in about the same financial position it would have been in if the infringement had not happened. But the damages award cannot be less than a reasonable royalty. You may not add anything to the amount of damages to punish an accused infringer or to set an example. You also may not add anything to the amount of damages for interest.

Damages are awarded on the sales of products that you find infringe or are used in a direct infringement.⁷³

While PureWick is not required to prove the amount of their damages with mathematical precision, PureWick must prove them with reasonable certainty. You may not award damages that are speculative, damages that are only possible, or damages that are based on guesswork.

The fact that I am instructing you on damages does not mean that the Court believes that one party or the other should win in this case. My instructions about damages are for your guidance only in the event you find in favor of the PureWick. You will need to address damages only if you find that one or more of the asserted claims are both not invalid and infringed.⁷⁴

⁷³ This paragraph was modified from the *ArcherDX* instructions to remove the portion that is not relevant to this issues in this case.

⁷⁴ See AIPLA Model Patent Jury Instructions, § 10.0 (2019); The Federal Circuit Bar Association Model Patent Jury Instructions § B.5 at 5.5 (2020).

B. DAMAGES – KINDS OF DAMAGES

There are several kinds of damages that are available for patent infringement.

One kind of damages is lost profits, that is, the additional profits that the patentee would have made if the defendant had not infringed. You may hear this referred to as the “but for” test – which means, “What profits would the patent owner have made ‘but for’ the alleged infringement?”

Another kind of patent damages is a reasonable royalty. A reasonable royalty is the amount that someone wanting to use the patented invention would have agreed to pay to the patent owner and that the patent owner would have accepted. A reasonable royalty is the minimum amount of damages that a patent owner can receive for an infringement.

In this case, for the 376 and 989 patents, PureWick seeks either (1) lost profits, with a reasonable royalty for PrimaFit products on which lost profits are not awarded, or (2) a reasonable royalty for all the alleged infringement of its 376 and 989 patents. For the 407 patent, PureWick seeks a reasonable royalty for the alleged infringement.

Regardless of the type of damages you may choose to award, you must be careful to ensure that award is no more and no less than the value of the patented invention.⁷⁵

⁷⁵ The Federal Circuit Bar Association Model Patent Jury Instructions § B.5 at 5.1 (2020).

C. DISPUTED: LOST PROFITS – “BUT FOR” TEST

PureWick is seeking lost profits damages in this case in connection with Sage’s sales of the PrimaFit.

To prove lost profits, PureWick must show a causal relationship between the infringement and PureWick’s loss of profit. In other words, PureWick must show that, but for the infringement, there is a reasonable probability that PureWick would have earned additional profits for the sale of its product. In this case, PureWick is alleging lost profit damages related to lost sales of its PureWick Female External Catheter product as a result of Sage selling the PrimaFit product. PureWick must prove this by a preponderance of the evidence, more likely than not. Part of your job is to determine what the parties who purchased the allegedly infringing product from Sage would have done if the alleged infringement had not occurred. It is important to remember that the profits I have been referring to are the profits allegedly lost by PureWick, not the profits, if any, made by Sage on the allegedly infringing sales.

PureWick has proven lost profits if you find that PureWick has proven each of the following factors by the more likely than not standard:

- (1) There was a demand for the patented product.
- (2) There was no available, acceptable, noninfringing substitute products.
- (3) PureWick had the manufacturing and marketing capacity to make any infringing sales actually made by Sage and for which the PureWick seeks an award of lost profits – in other words, that PureWick was capable of satisfying the demand.
- (4) The amount of profit that PureWick would have made if it were not for Sage’s infringement.

[Plaintiff's Additional Proposal:^{76,77} If you find that there were only two suppliers in the market, PureWick does not need to prove the first two factors. In a two-supplier market it is enough to show that there were two suppliers, that PureWick was capable of satisfying the demand, and the amount of profit PureWick would have made if Sage had not infringed. If you find that

⁷⁶ Plaintiff contends that a two-supplier market exists in this case and therefore it is proper to instruct the jury on this issue. The *Panduit* factors are not the only test for proving lost profits. See *Micro Chem., Inc. v. Lextron, Inc.*, 318 F.3d 1119, 1122 (Fed. Cir. 2003). “[U]nder the two-supplier test, a patentee must show: 1) the relevant market contains only two suppliers, 2) its own manufacturing and marketing capability to make the sales that were diverted to the infringer, and 3) the amount of profit it would have made from these diverted sales.” *Id.* at 1124. Plaintiff’s proposed addition to the instruction concerning a two-supplier market is adapted from the Court’s Final Jury Instructions read to the jury in *TrustID, Inc. v. Next Caller Inc.*, No. 18-172 (MN), D.I. 295 (July 16, 2021).

All of Defendant’s arguments against this instruction are dependent on disputed facts. For example, Defendant’s assertion that “PureWick concedes that there is no two-supplier market” is incorrect and is based solely on Defendant’s interpretation of the facts. Similarly, Defendant’s arguments about the existence of non-infringing alternatives are all factual disputes, as the Court recognized in denying Defendant’s motion for summary judgment of no lost profits. Further, just because PureWick has offered evidence rebutting Defendant’s contentions regarding alleged non-infringing alternatives obviously does not mean that PureWick either agrees that there are non-infringing alternatives, or that they are relevant here. PureWick intends to present evidence of a two-supplier market and the jury should be instructed on the law to apply to that evidence.

⁷⁷ Defendant contends this addition to the jury instruction is inappropriate and misleading to the jury for this particular case. PureWick concedes that there is no two-supplier market because it has already acknowledged that there are customers that would not have purchased PureWick if a PrimaFit was not available. (D.I. 211_Ex. 38 at ¶ 53-54 n. 104). Plaintiff’s damages expert has not explicitly relied on the two-supplier market theory. Furthermore, despite the fact that PureWick’s proposed instruction states that if the jury finds that there is a two-supplier market “PureWick does not need to prove the first two factors [listed above],” one of which is non-infringing alternatives, PureWick’s experts have provided opinions as to non-infringing alternatives. Additionally, PureWick requested and received the opportunity to take multiple additional depositions of Sage employees on non-infringing alternatives in the weeks before trial. (D.I. 279 at p. 39-41). Moreover, PureWick improperly relies on this theory. As the Federal Circuit explicitly stated in *Micro Chem*, even if there a two-supplier market, courts must still consider whether there is “another available, noninfringing substitute” because “customers may have selected the infringer’s available, noninfringing alternative over the patented invention.” 318 F.3d at 1125. In this case, Sage has proffered multiple non-infringing alternatives that Sage itself either sells (i.e. Microclimate Body Pad) or could have readily implemented.

PureWick establishes those three factors, you may presume that PureWick is entitled to lost profits. Sage may rebut this presumption by showing that PureWick reasonably would not have made some or all of the diverted sales “but for” the infringement.]

D. LOST PROFITS – DEMAND

The first factor asks whether there was demand for the patented product in the relevant market. PureWick can prove demand for the patented product by showing significant sales of PureWick's own patented product. PureWick also can prove demand for the patented product by showing significant sales of Sage's product that is covered by one or more of the asserted claims of the 376 or 989 patents. To use sales of Sage's product as proof of this demand, however, PureWick's and Sage's products must be sufficiently similar to compete against each other in the same market or market segment.

E. DISPUTED: LOST PROFITS – NON-INFRINGEMENT SUBSTITUTES-ACCEPTABLE NON-INFRINGEMENT SUBSTITUTE PRODUCTS⁷⁸

The second factor asks whether non-infringing, acceptable substitutes for PureWick's product [**Plaintiff's Proposal:** ⁷⁹ competed with Sage's infringing product; **Defendant's Proposal:** are]⁸⁰ in the marketplace and the impact of such substitutes on the marketplace absent the sale of Sage's products. If you find that competitors other than PureWick (including Sage) would likely have captured some or all of the sales of the allegedly infringing products, even despite a difference in the products, then PureWick is not entitled to lost profits on those sales.

To be an "acceptable, noninfringing substitute," a product must have [**Plaintiff's Proposal:**⁸¹ the; **Defendant's Proposal:** one or more⁸²] advantages of the patented invention that were important to people who purchased the infringing products. [**Defendant's Additional**

⁷⁸ AIPLA Model Patent Jury Instructions, section 10.2.1.4 (2019); Federal Circuit Bar Association Model Patent Jury Instruction § B.5.2 (May 2020).

⁷⁹ Plaintiff's proposed language is taken from the Court's Final Jury Instructions read to the jury in *ArcherDX, LLC et al. v. Qiagen Sciences, LLC et al.*, No. 18-1019 (MN), D.I. 462 (Aug. 27, 2021).

⁸⁰ Defendant contends that the requirement that a non-infringing alternative "competed with Sage's product" is legally inaccurate given the facts of this case. *Presidio* expressly states that the "correct inquiry . . . is whether a non-infringing alternative would be acceptable compared to the patent owner's product, not whether it is a substitute for the infringing product." *Presidio Components, Inc. v. Am. Tech. Ceramics Corp.*, 875 F.3d 1369, 1380 (Fed. Cir. 2017). Moreover, an acceptable non-infringing alternative does not have to be on the market to be available. *Grain Processing Corp. v. Am. Maize-Prod. Co.*, 185 F.3d 1341, 1356 (Fed. Cir. 1999) ("an acceptable substitute not on the market during the infringement may nonetheless become part of the lost profits calculus and therefore limit or preclude those damages").

⁸¹ Plaintiff's proposed language is taken from the Court's Final Jury Instructions read to the jury in *ArcherDX, LLC et al. v. Qiagen Sciences, LLC et al.*, No. 18-1019 (MN), D.I. 462 (Aug. 27, 2021).

⁸² Defendant's proposed language is consistent with the AIPLA Model jury instructions which states that "[t]o be an acceptable substitute, the [[product]/[method]] must have had one or more of the advantages of the patented invention . . ." AIPLA Model Patent Jury Instructions, section 10.2.1.4 (2019).

Proposal:⁸³ The acceptable substitute may be a product that involved a modification of the infringing product to avoid infringement or the removal of at least one feature of the invention from the product. If you determine that some of Sage's customers would just as likely have purchased an acceptable non-infringing substitute, then PureWick has not shown it lost those sales but for Sage's infringing sales.]

If purchasers of [**Plaintiff's Proposal:** Sage's products; **Defendant's Proposal:** an alleged infringer's product] were motivated to buy that product because of features only available from that product and PureWick's patented product, then some other, alternative product is not an acceptable substitute, even if it otherwise competed with PureWick's and Sage's products. On the other hand, if the realities of the marketplace are that competitors other than PureWick would likely have captured the sales made by Sage, despite a difference in the products, then PureWick is not entitled to lost profits on those sales.

Even if you find that PureWick's and Sage's products were the only ones with the advantages of the patented invention, PureWick is nonetheless required to prove to you that PureWick, in fact, would have made Sage's infringing sales.

⁸³ Defendant's proposed language is consistent with AIPLA Model Patent Jury Instructions, section 10.2.1.4 (2019). Defendant's proposed language also accounts for evidence expected to be presented at trial as to modifications that Sage could have made to its accused products, thus resulting in non-infringing alternatives.

F. DISPUTED: LOST PROFITS – NON-INFRINGEMENT SUBSTITUTES – AVAILABILITY

[**Plaintiff's Proposal**⁸⁴: The acceptable substitute, in addition to being either licensed or non-infringing, must have been available during the damages period. An alternative product may be considered “available” as a potential substitute even if the product was not actually on sale during the infringement period. But, if the acceptable substitute was not sold during the damages period, then Sage must show by a preponderance of the evidence that, during the damages period, a competitor or Sage had all the necessary equipment, materials, know-how, and experience to design and manufacture the acceptable substitute.; **Defendant's Proposal**:⁸⁵ An alternative product may be considered “available” as a potential substitute even if the product was not actually on sale during the infringement period. Factors suggesting the alternative was available include whether the material, experience, and know-how to make or use the alleged substitute were readily available at the time of infringement.]

Factors suggesting the alternative was not available include whether the material was of such high cost as to render the alternative unavailable and whether an alleged infringer had to design or invent around the patented technology to develop an alleged substitute.⁸⁶

⁸⁴ Plaintiff's proposed instruction is taken nearly verbatim from the AIPLA Model Patent Jury Instructions, section 10.2.1.4 (2019). Defendant's instruction is prejudicial because it omits the important portion of the AIPLA Model Patent Jury Instructions that states that Defendant carries the burden of proving that an alleged alternative was available when it was not sold during the damages period, as is the case here.

⁸⁵ Defendant's proposed instruction is taken from the Federal Circuit Bar Association Model Patent Jury Instruction § B.5.2 (May 2020) and is the same as the Court's instruction in *ArcherDX*. Plaintiff's proposal prejudices Defendant and creates confusion for the jury because it sets forth a burden of proof for Defendant, while the ultimate burden of proof for Plaintiff in proving its damages claim is not mentioned and is not repeated in the multiple instructions related to damages. Plaintiff's proposal deletes factors for determining whether an alternative is available, while retaining factors for determining whether an alternative is not available.

⁸⁶ Federal Circuit Bar Association Model Patent Jury Instruction § B.5.2 (May 2020).

G. LOST PROFITS – CAPACITY

The third lost profits factor asks whether PureWick had the manufacturing and marketing ability to actually make the sales it allegedly lost due to Sage's infringement. PureWick must prove that it could have supplied the additional products needed to make the sales it said it lost, or that someone working with PureWick could have supplied the additional products. PureWick also must prove that it more likely than not had the ability to market and sell these additional products.

H. LOST PROFITS – AMOUNT OF PROFIT

PureWick may calculate the amount of its lost profits by calculating its lost sales and subtracting from that amount any additional costs or expenses that PureWick would have had to pay to make the lost sales. The amount of lost profits cannot be speculative, but it need not be proven with unerring certainty.

I. DISPUTED: REASONABLE ROYALTY – ENTITLEMENT

[Plaintiff’s Proposed Instruction⁸⁷: In this case, PureWick is also seeking damages in the amount of a reasonable royalty on Sage’s PrimaFit and PrimoFit products. In addition to considering the issue of a reasonable royalty on the PrimoFit product, if you find that PureWick has not proven its claim for lost profits concerning the PrimaFit product, or if you find that PureWick has proven its claim for lost profits for only a portion of the infringing sales, then you must also consider the issue of a reasonable royalty for infringing sales for which PureWick has not been awarded lost profit damages.]

[Defendant’s Proposal:⁸⁸ If you find that a patent claim is infringed and not invalid, PureWick is entitled to at least a reasonable royalty to compensate it for that infringement.

If you find that PureWick has not proven its claim for lost profits or has proven its claim for lost profits for only a portion of the infringing sales, then you must also consider the issue of a reasonable royalty for infringing sales for which PureWick has not been awarded lost profit damages.]

⁸⁷ Plaintiff’s proposed instruction is adapted from the Final Jury Instructions read to the jury in *ArcherDX, LLC et al. v. Qiagen Sciences, LLC et al.*, No. 18-1019 (MN), D.I. 462 (Aug. 27, 2021) and clarifies that it is seeking lost profits for the PrimoFit product as well as for the PrimaFit product (to the extent it does not prove some or all of its claim for lost profits relating to the PrimaFit product). Defendant’s proposed instruction is confusing and prejudicial because it fails to mention the PrimoFit product.

⁸⁸ Defendant’s proposed instruction is taken from the the Federal Circuit Bar Association Model Patent Jury Instructions § B.5 at 5.5 (2020). Plaintiff’s proposed instruction risks confusing the jury that it could award both royalty and lost profit damages for the same allegedly infringing sale. Defendant’s proposed instruction is not confusing or prejudicial because it addresses allegedly infringing sales generally, which includes both PrimaFit and PrimoFit. The *ArcherDX* instruction (D.I. 462 at p. 47) does not address two products as Plaintiff’s have edited it above.

J. REASONABLE ROYALTY - DEFINITION

A royalty is a payment made to a patent holder in exchange for the right to make, use, or sell the claimed invention. A reasonable royalty is the royalty payment that would have resulted from a hypothetical negotiation between the patent owner and the alleged infringer just before the infringement began. In considering this hypothetical negotiation, you should focus on what the expectations of the patent holder and the infringer would have been if they had entered into an agreement at that time, and if they had acted reasonably in their negotiations. In determining this, you must assume that both parties to the hypothetical negotiation believed the patent was valid and infringed and that both parties were willing to enter into an agreement. You should also presume that the parties had full knowledge of the facts and circumstances surrounding the infringement at the time of the hypothetical negotiation.

The reasonable royalty you determine must be a royalty that would have resulted from the hypothetical negotiation, and not simply a royalty either party would have preferred.

Evidence of things that happened after the infringement first began can be considered in evaluating the reasonable royalty only to the extent that the evidence aids in assessing what royalty would have resulted from a hypothetical negotiation. Although evidence of the actual profits an alleged infringer made may be used to determine the anticipated profits at the time of the hypothetical negotiation, the royalty may not be limited or increased based on the actual profits the alleged infringer made.⁸⁹

In determining the reasonable royalty, you should consider all the facts known and available to the parties at the time the infringement began. No one fact is dispositive and you

⁸⁹ AIPLA Model Patent Jury Instructions, section 10.2.5.2 (2019).

should consider the evidence that has been presented to you in this case. You may also consider any other factors that in your mind would have increased or decreased the royalty the alleged infringer would have been willing to pay and the patent holder would have been willing to accept, acting as normally prudent business people.

K. REASONABLE ROYALTY: RELEVANT FACTORS TO THE HYPOTHETICAL NEGOTIATION

In determining the amount of a reasonable royalty, you may consider evidence on any of the following factors, in addition to any other evidence presented by the parties on the economic value of the patent. This is not every possible factor, but it will give you an idea of the kinds of things to consider in setting a reasonable royalty.

1. Any royalties received by the licensor for the licensing of the Asserted Patents, proving or tending to prove an established royalty.
2. The rates paid by Sage to license other patents comparable to the Asserted Patents.
3. The nature and scope of the license, as exclusive or non-exclusive, or as restricted or non-restricted in terms of its territory or with respect to whom the manufactured product may be sold.
4. The licensor's established policy and marketing program to maintain its right to exclude others from using the patented invention by not licensing others to use the invention, or by granting licenses under special conditions designed to preserve that exclusivity.
5. The commercial relationship between the licensor and the licensee, such as whether or not they are competitors in the same territory in the same line of business.
6. The effect of selling the patented product in promoting other sales of the licensee; the existing value of the invention to the licensor as a generator of sales of its non-patented items; and the extent of such collateral sales.
7. The duration of the Asserted Patents and the term of the license.
8. The established profitability of the product made under the Asserted Patents; its commercial success; and its popularity.

9. The utility and advantages of the patented invention over the old modes or devices, if any, that had been used for achieving similar results.
10. The nature of the patented invention; the character of the commercial embodiment of it as owned and produced by or for the licensor; and the benefits to those who have used the invention.
11. The extent to which Sage has made use of the invention; and any evidence that shows the value of that use.
12. The portion of the profit or of the selling price that may be customary in the particular business or in comparable businesses to allow for the use of the invention or analogous inventions.
13. The portion of the profit that arises from the patented invention itself as opposed to profit arising from unpatented features, such as the manufacturing process, business risks, or significant features or improvements added by the accused infringer.
14. The opinion testimony of qualified experts.
15. The amount that a licensor (such as PureWick) and a licensee (such as Sage) would have agreed upon (at the time the infringement began) if both sides had been reasonably and voluntarily trying to reach an agreement; that is, the amount which a prudent licensee – who desired, as a business proposition, to obtain a license to manufacture and sell a particular article embodying the patented invention – would have been willing to pay as a royalty and yet be able to make a reasonable profit and which amount would have been acceptable by a patentee who was willing to grant a license.
16. Any other economic factor that a normally prudent business person would, under similar circumstances, take into consideration in negotiating the hypothetical license.

No one factor is dispositive, and you can and should consider the evidence that has been presented to you in this case on each of the factors. You may also consider any other factors that in your mind would have increased or decreased the royalty the infringer would have been willing to pay, and the patent holder would have been willing to accept, acting as normally prudent business people.⁹⁰

⁹⁰ AIPLA Model Patent Jury Instructions, section 10.2.5.3 (2019).

L. DAMAGES – APPORTIONMENT

The amount you find as damages must be based on the value attributable to the patented invention, as distinct from unpatented features of the accused product or other factors such as marketing or advertising, PureWick's size or market position. A royalty compensating the patent holder for damages must reflect the value attributable to the infringing features of the product, and no more. The process of separating the value of the allegedly infringing features from the value of all other features is called apportionment. When the accused infringing products have both patented and unpatented features, your award must be apportioned so that it is based only on the value of the patented features, and no more.⁹¹

⁹¹ The Federal Circuit Bar Association Model Patent Jury Instructions § B.5 at 5.12 (2020).

M. REASONABLE ROYALTY – MULTIPLE PATENTS

If you find that Sage infringed multiple patents, even by a single infringing act, and if you award a reasonable royalty for infringement, then you may award separate royalties to PureWick for each patent that was infringed. You also may consider evidence of the number of patent licenses that are needed for the allegedly infringing product and the effect on the hypothetical negotiation of having to pay a royalty for each of those licenses.⁹²

⁹² This instruction taken from AIPLA Model Patent Jury Instructions, section 10.2.5.6 (2019).

N. REASONABLE ROYALTY: TIMING

Damages are not based on a hindsight evaluation of what happened, but on what the parties to the hypothetical license negotiations would have agreed upon. Nevertheless, evidence relevant to the negotiation is not necessarily limited to facts that occurred on or before the date of the hypothetical negotiation. You may also consider information the parties would have foreseen or estimated during the hypothetical negotiation, which may under certain circumstances include evidence of usage after infringement started, license agreements entered into by the parties shortly after the date of the hypothetical negotiation, profits earned by the infringer, and non-infringing alternatives.

O. REASONABLE ROYALTY: AVAILABILITY OF NON-INFRINGEMENT SUBSTITUTES

In determining a reasonable royalty, you may also consider evidence concerning the availability and cost of acceptable non-infringing substitutes to the patented invention. An acceptable substitute must be a product that does not infringe the patent.

P. DISPUTED: DATE OF COMMENCEMENT OF DAMAGES

In determining the amount of damages, you must determine when the damages began. Damages commence on the date that Sage has both infringed and been notified of the alleged infringement of an asserted patent.

[Defendant's Additional Proposal:^{93,94} If you find that PureWick has proven that Sage has infringed a valid claim of the 376 patent and is entitled to damages for the 376 patent, the date that damages would begin for that patent is August 12, 2019.

If you find that PureWick has proven that Sage has infringed a valid claim of the 989 patent and is entitled to damages for the 989 patent, the date that damages would begin for that patent is August 27, 2019.

If you find that PureWick has proven that Sage has infringed a valid claim of the 407 patent and is entitled to damages for the 407 patent, the date that damages would begin for that patent is January 1, 2020.^{95]}

⁹³ Defendant contends that PureWick's proposal standing alone is confusing given that there are multiple patents in this case, all of which have undisputed damages start dates. PureWick has conceded that it did not mark its patents with the 376 patent number until after the Complaint was filed (August 14, 2019). (D.I. 207 Ex. 11 at 27-28.) However, PureWick would not agree to Sage's proposal that references August 12, 2019 (the date of the lawsuit filing), as the first damages date for the 376 patent (even though its expert does not seek damages prior to that date). (D.I. 211 Ex. 38 at ¶64 n. 131 & Leonard Ex. 1). PureWick also refused to include the starting damages date for the other patents. There is no reason to confuse the jury into thinking that there is some other damages start dates rather than ones listed here. Sage reserves the right to add an additional instruction to the extent necessary if PureWick is permitted to dispute the dates that damages begin even though it had not previously done so.

⁹⁴ Plaintiff does not believe Sage's additional instruction is necessary, especially in light of the fact that Defendant's additional instructions are not in the Federal Circuit Bar Association Model Patent Jury Instructions § B.5 at 5.10 (2020), which Defendant cites as the authority for this instruction.

⁹⁵ Adapted from The Federal Circuit Bar Association Model Patent Jury Instructions § B.5 at 5.10 (2020).

Now we will have closing arguments and I will read the rest of the instructions to you after that.

IV. DELIBERATIONS AND VERDICT

A. DELIBERATION AND VERDICT – INTRODUCTION

Now let me finish up by explaining some things about your deliberations in the jury room, and your possible verdicts.

Once you start deliberating, do not talk to the jury officer, or to me, or to anyone else except each other about the case. If you have any questions or messages, you must write them down on a piece of paper, sign them, and then give them to the jury officer. The officer will give them to me, and I will respond as soon as I can. I may have to talk to the lawyers about what you have asked, so it may take me some time to get back to you. Any questions or messages normally should be sent to me through your foreperson, who by custom of this Court is Juror No. 1.

One more thing about messages. Do not ever write down or tell anyone how you stand on your votes. For example, do not write down or tell anyone that you are split 4-4, or 6-2, or whatever your vote happens to be. That should stay secret until you are finished.

B. DISPUTED: UNANIMOUS VERDICT

Your verdict must represent the considered judgment of each juror. In order for you as a jury to return a verdict, it is necessary that each juror agree to the verdict. Your verdict must be unanimous.

It is your duty, as jurors, to consult with one another and to deliberate with a view towards reaching an agreement, if you can do so consistent with your individual judgment. Each of you must decide the case for yourself, but do so only after an impartial consideration of the evidence with your fellow jurors. In the course of your deliberations, do not hesitate to reexamine your own views and change your opinion, if convinced it is erroneous. But do not surrender your honest conviction as to the weight or effect of evidence solely because of the opinion of your fellow jurors, or for the purpose of returning a verdict. Remember at all times that you are not partisans. You are judges of the facts. Your sole interest is to seek the truth from the evidence in the case.

A verdict form has been prepared for you. I will review it with you in a minute.

[Defendant's Proposal: You need to answer the questions on the verdict form regarding infringement and invalidity for each patent-in-suit. You should answer the questions about willful infringement for 376 patent, and 989 patent, only if you find at least one of the asserted claims for each of those patents are both infringed and not proven invalid. You should answer the questions about damages for the 376 patent, 989 patent and 407 patent, only if you find at least one of the asserted claims of each of those patents are both infringed and not proven invalid.]^{96,97}

⁹⁶ Defendant's instruction is adapted from *E.I. Du Pont Nemours and Co. v. Unifrax I LLC*, No. 14-1250-RGA, D.I. 325, §7.2 (D. Del. May 15, 2017).

⁹⁷ Plaintiff does not believe that the bracketed text added to this instruction by Defendant is necessary as it is redundant of previous instructions. Defendant also fails to cite any support for this addition, which deviates from the Final Jury Instructions read to the jury in *ArcherDX, LLC et al. v. Qiagen Sciences, LLC et al.*, No. 18-1019 (MN), D.I. 462 (Aug. 27, 2021).

You will take this form to the jury room and when you have reached unanimous agreement as to your verdict, you will have your foreperson fill in, date and sign the form. You will then return to the courtroom and my deputy will read aloud your verdict.

And I will remind you that nothing said in these instructions, and nothing in the verdict form, is meant to suggest or convey in any way or manner any intimation as to what verdict I think you should find. What the verdict shall be is your sole and exclusive duty and responsibility.

C. DUTY TO DELIBERATE

Now that all the evidence is in and the arguments are completed, you are free to talk about the case in the jury room. In fact, it is your duty to talk with each other about the evidence, and to make every reasonable effort you can to reach unanimous agreement. Talk with each other, listen carefully and respectfully to each other's views, and keep an open mind as you listen to what your fellow jurors have to say. Try your best to work out your differences. Do not hesitate to change your mind if you are convinced that other jurors are right and that your original position was wrong.

But do not ever change your mind just because other jurors see things differently, or just to get the case over with. In the end, your vote must be exactly that – your own vote. It is important for you to reach unanimous agreement, but only if you can do so honestly and in good conscience.

No one will be allowed to hear your discussions in the jury room, and no record will be made of what you say. So, you should all feel free to speak your minds.

Listen carefully to what the other jurors have to say, and then decide for yourself.

D. SOCIAL MEDIA

During your deliberations, you must not communicate with or provide any information to anyone by any means about this case. You may not use any electronic device or media, such as the telephone, a cell phone, smartphone, iPhone, iPad, tablet or computer, the Internet, any Internet service, any text or instant messaging service, any Internet chat room, blog or website such as Facebook, LinkedIn, YouTube, Instagram, Snapchat or Twitter to communicate to anyone any information about this case or to conduct any research about this case until I accept your verdict. In other words, you cannot talk to anyone on the phone, correspond with anyone, or electronically communicate with anyone about this case. You can only discuss the case in the jury room with your fellow jurors during deliberations.

E. COURT HAS NO OPINION

Let me finish up by repeating something that I said to you earlier. Nothing that I have said or done during this trial was meant to influence your decision in any way. You must decide the case yourselves based on the evidence presented.